Ramsey (Drew) Falconer, MD

Co-Director, Movement Disorders Specialist
Inova Parkinson's and Movement Disorders Center

985-630-1419
Drew.Falconer@inova.org

"Improving Parkinson's Outcomes through use of Modern Therapies: An Update on Advancements in Treatment" – Inova Neuroscience Regional Program – *March 2019*

"Neurorestoration, the new frontier in Parkinson's Disease" – National Neuroscience Review – *May 2019*

"Advancements in the Treatment of Parkinson's Disease" – Movement Disorders Center Bi-yearly Patient Education Event – *October 2019*

"Best Practices for Parkinson's Disease treatment" – Abbott Neuromodulation Workforce Development – *January 2020*

"Being Clinical Partners in the GPi" – Abbott Neuromodulation NSM – *February 2020*

"Parkinson's and Deep Brain Stimulation" – Abbott Neuromodulation National Education Webinar – *April 2020*

"Advanced Medical Management of Parkinson's Disease" – Inova Regional Webinar – *April 2020*

"Living Better with Parkinson's Disease through Updated Treatments" – Inova Regional Webinar – *May 2020, June 2020*

"PD Fundamentals and Applying Updated Medical Options" – Inova Neuroscience Regional Program – *May 2020*

"DBS and other Advanced Therapies" – Inova Regional Webinar – *May 2020, June 2020*

"Expanding Treatments through Technology (DBS, Duopa and more)" – Inova Neuroscience Regional Program – *May 2020*

"Non-medical treatments: exercise, diet and more" – Inova Regional Webinar – *July 2020*

"Hospitalization and Parkinson's Disease" – Inova Regional Webinar – *August 2020*

Drew Falconer, MD
Board Certified Neurologist, Movement Disorders Specialist

1500 N. Beauregard St, #300
Alexandria, VA 22311

(985) 630-1419
Drew.Falconer@inova.org

Ramsey (Drew) Falconer, MD Case Log 2018 – present

1.	7/5/2018	Eastern Alliance	Peer records review
2.	11/29/2018	US Justice Dept.	1:18-cv-784 (LMB/IDD)
3.	11/27/2019	Nationwide	PW Circuit Court Case no.: CL19-237
4.	11/19/2019	Nationwide	Fairfax Circuit Court Case no.: CL2017-13872
5.	11/27/2019	Nationwide	Fairfax County Court Case no.: CL-2018-18319
6.	1/10/2020	Nationwide	Loudoun County Court Case no: 107CL00114039-00
7.	3/17/2020	Nationwide	Loudoun County Court Case no: 18003080-00
8.	3/21/2020	Nationwide	Fairfax County Court Case no.: CL2019-10455
9.	5/15/2020	Geico	Fairfax County Court Case no: CL2020-0673
10.	8/2/2020	Nationwide	Pending case
11.	9/10/2020	Gammon&Grange	Medical review case JK71018
12.	11/30/2020	RossFellerCaseyLLP	Medical review case RDZ
13.	1/20/2021	RossFellerCaseyLLP	Medical review case MM
14.	2/24/2021	Geico	Case No.: CL-2019-0016494
15.	4/12/2021	Beasley FirmLLp	Medical review case MT
16.	4/11/2020	FTC	Federal Trade Comm. Matter No. X200051

Attachment B

METABOLIC Plan of Care

CELLULAR THERAPY

DIETARY SUPPLEMENT PRODUCTS

DetoxHerb-1, DetoxHerb-2, DetoxHerb-PI, DetoxHerb-NR, AnterFeeron-1, AnterFeeron-2, C_RProtein, HyProtein-1, Hyprotein-2, HyProtein-3, HyProtein-4, LyProtein, ImunStem, and Aktiffvate

COMPANY

Golden Sunrise Nutraceutical, Inc.
219 North E Street
PORTERVILLE, CA 93257 * U.S.A.
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

PLEASE DOWNLOAD AT

www.goldensunrisenutraceutical.com

"TREATMENT"

TABLE OF CONTENTS

1.0 INTRODUCTION

Golden Sunrise Nutraceutical metabolic therapies will treat ***Serious or Life-threatening*** conditions. These conditions result from an accumulation of toxins in the body from food additives, preservatives, pesticides, prescription drugs, and industrial pollution that disrupt the immune system and cell metabolism. Regenerating the cellular metabolic abnormalities with plant based botanicals found in the ***METABOLIC Plan of Care*** is the basis for the remarkable improvement for human health.

The herbal supplements created by Golden Sunrise Nutraceutical are designated as a Regenerative Medicine Advance Therapy (RMAT) by the Food & Drug Administration (FDA). The FDA formed a new department called Regenerative Medicine Advance Therapy because of the law enacted by the 114th United States Congress in December 2016 called the 21st Century Cures Act. These herbal supplements are able to penetrate the cells at the cellular level without any disruption or damage to the cells because they are recognized as food. This food provides the cells with the necessary building blocks for the cells to repair and rejuvenate themselves and flush out the accumulated toxins in the cells. They provide the building blocks for the cells to transform the crippled metabolic pathways back to the normal condition and allow the cells to perform the normal functions which they were designed to perform. ***Serious or Life-threatening*** conditions are either modified, reversed or cured (Cures Act p.180).

Golden Sunrise Nutraceutical products and treatments improve genetic ***Telomeres*** for cellular regeneration which increases the overall-health of the body and can increase human longevity.

2.0 INDICATIONS AND USAGE

The administration of herbal / botanical ***METABOLIC Plan of Care*** treatments for human health has led to the benefit of metabolic syndrome treatments from plant based materials. ***ImunStem***, ***Aktiffvate***, ***DetoxHerbs***, and ***AnterFeerons*** treatments have been of great value to patients that only use herbal / botanical products for overall health. This has led to improved outcomes for patients.

METABOLIC Plan of Care treatment begins with the use of ***ImunStem*** and ***Aktiffvate*** to improve the immune system function. Then the administration of ***DetoxHerbs*** are given to flush the system and aim at arresting the development of the metabolic disorders. The treatments are continued in order to support the elimination of metabolic disorders.

FIRST AND FOREMOST, ***IMUNSTEM***, ***AKTIFFVATE***, AND ***METABOLIC Plan of Care***, MUST BE ADMINISTERED UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Once a medical evaluation of the patient has been completed and reviewed, those patients whose medical history and current medical condition is appropriate for treatment with ***METABOLIC Plan of Care*** will receive the product as follows:

3.0 INSTRUCTIONS FOR THE TREATMENT

Before starting the ***ImunStem*** and ***Aktiffvate*** the patient must be in stable condition and the diagnosis must be established as thoroughly as possible. This prepares the treating health professional, and the patient as well, for expected changes that can occur because of the disease process, thus avoiding possible confusion which might erroneously be attributed to the Golden Sunrise Nutraceutical herbal / botanical products. A thorough history (and physical exam as well) is necessary because the health professional can often appreciate improvement in areas that are ignored by the patient. For example, the patient may be discouraged by little improvement in their hand arthritis but when asked, they may acknowledge improvement in their back pain, or energy level or insomnia, etc.

The ***ImunStem*** and ***Aktiffvate*** are the primary herbs of the whole program to begin the detoxification and repairing of the cells at the cell level. They prepare the immune system to respond appropriately to the Golden Sunrise Nutraceutical herbal / botanical products used in the ***METABOLIC Plan of Care*** protocol. Noticeable changes will occur when using ***ImunStem*** and ***Aktiffvate***, whether it be increased energy, better ability to focus and concentrate, better sleep, improved joint pain, etc. In perhaps 2–3% of patients starting the ***ImunStem*** and ***Aktiffvate***, the detoxification process may be more profound and may cause symptoms consisting of mild skin rashes, swelling in the face, hands or legs, headaches, poor energy, diarrhea, etc. These should be recognized not as a side-effect, but actually, the beginning of the healing process in the cells. This is caused by the release of toxins. These symptoms may last 2–7 days. Depending on the vigor of these symptoms, the dose may need to be reduced, or stopped altogether, for varying lengths of time. When resuming the ***ImunStem*** and the ***Aktiffvate***, the dose usually needs to be started at a reduced dose.

In the ***METABOLIC Plan of Care*** the "Treatment, dosage and administration" call for "an initial five (5) sessions". Each session has two (2) bottles. The first bottle in each session are designed to reinforce and build upon what the ***ImunStem*** and ***Aktiffvate*** have started, e.g. nourishing the cells and flushing the toxins. But it is done in a much more powerful way. The second bottle in each session prompts the natural flushing action of the body, that is vomiting and / or diarrhea to flush out the toxins (there can also be nasal discharge and coughing up sputum) (of interest these can be administered through a gastric tube or nasogastric tube. However, if the gastric tube was placed for dysphagia, then use of the gastric tube is contraindicated because of possible aspiration problem with vomiting). The general strength of the patient and their ability to comply with the ***METABOLIC Plan of Care*** protocol may limit them to the use of only the ***ImunStem*** and ***Aktiffvate***.

4.0 TREATMENT, DOSAGE, AND ADMINISTRATION

First, ***ImunStem*** and ***Aktiffvate*** are taken simultaneously at ½ – ¾ dropperful, 2–4 times a day, for approximately two (2) weeks before ***DetoxHerb*** is administered. These products can improve the function of the immune system, as well as overall health. This step is very important, as it will maximize the effect of the ***DetoxHerbs***. An initial five (5) sessions of the

DetoxHerbs and ***AnterFeerons*** are given which are designed to be given very 2–4 weeks (it is highly recommended every two (2) weeks because of the seriousness of the condition). On occasion, the interval between ***DetoxHerb*** sessions is not rigid, and although it is recommended to be done every 2–4 weeks, the session can be up to 1–2 months apart. Once the five (5) sessions are completed, and the patient's condition is stable and shows appropriate improvement, other Golden Sunrise Nutraceutical products will be added, usually at 2–4 weeks intervals. These additional ***DetoxHerb*** sessions (up to four (4) or five (5) additional treatments) will be included and are guided by the patient's response and condition.

These are high quality herbal products, some of which include ***AnterFeeron***, ***C_RProtein***, ***HyProtein***, and ***LyProtein***. Blood tests are at the discretion of the health professional, but it is recommended that a baseline of blood tests have been done before starting the ***ImunStem*** and ***Aktiffvate***. Further blood tests could be done later, again at the discretion of the health professional, at two (2) weeks or four (4) weeks, etc. Before starting the five (5) initial treatment sessions with the ***DetoxHerbs***, it is extremely important to verify if the patient is constipated. This needs to be corrected as well as possible beforehand, because the ability of the bowels to flush is the primary way of ridding the body of the toxins.

The "initial five (5) sessions" for the ***DetoxHerbs*** and ***AnterFeerons*** consist of:

Liquids
Session #1: ***DetoxHerb-1*** and ***DetoxHerb-2***

Liquids
Session #2: ***DetoxHerb-1*** and ***DetoxHerb-2***, or ***AnterFeeron-1*** and ***AnterFeeron-2***

Capsules and Liquids
Session #3, #4, & #5: ***DetoxHerb-PI*** and ***DetoxHerb-NR***, or ***AnterFeeron-1*** and ***AnterFeeron-2***

Each session is preferably 2-4 weeks apart. The interval may be shorter if the patient is extremely sick, but stable enough to tolerate the vomiting / diarrhea process.

The interval between ***DetoxHerb*** sessions is not rigid and although it is recommended to be every 2–4 weeks apart, they can be up to 1–2 months apart. The recommended sequence of the Golden Sunrise Nutraceutical herbal / botanical products can be interrupted with a different herbal / botanical products, usually ***AnterFeeron-1*** and ***AnterFeeron-2*** in either session #2, #4, or session #5, if the patient is not showing the expected flushing response of vomiting and / or diarrhea. A poor flushing response indicates that the patient is not ridding the body of the toxins appropriately. What is not "enough"? Perhaps only one (1) or two (2) episodes of diarrhea / bowel movements? It should be noted, however, that it is common not to have any vomiting in these sessions, so diarrhea episodes are more telling of the effectiveness of each session. The

reason to interject the ***AnterFeeron*** early into the sequence is because it usually promotes the desired flushing response (besides fighting infection).

The other very important information to monitor after each session are the patient's symptoms. Generally, they should feel stronger or more energy, etc. within 1–2 days after each session, indicating a proper response to each session as well. Frequently the lab / scanning results will lag behind the improvement in the patient's symptoms.

For the liquid ***DetoxHerbs*** and ***AnterFeerons***, it is important to instruct the patient to walk around, if they can, in 5–10 minutes after swallowing the first one fluid ounce (1 fl.oz.) bottle. In this short time there is frequently a better alertness or sense of energy, and if there are any pain issues, they are noticeably improved or completely resolved. Pointing this out to the patient is a quick positive reinforcer and encouragement of the effectiveness of the Golden Sunrise Nutraceutical herbal / botanical products. Perhaps five (5%) percent of patients will also notice, after the first bottle, better visual acuity or a "brightness" in the colors around them (indicating penetration of the Golden Sunrise Nutraceutical herbs across the blood-brain barrier into the central nervous system).

The duration of the flushing with the vomiting / diarrhea, generally lasts from 6-18 hours and rarely up to forty-eight (48) hours. The onset and duration of the vomiting / diarrhea after the second bottle in each session, varies not only for each person, but may also vary for the same person from session to session. Usually the onset is within thirty (30) minutes after ingesting the second bottle in each session, but it may not begin perhaps for up to six (6) hours. The ***ImunStem*** and ***Aktiffvate*** should not be taken on the same day of the session (the ***ImunStem*** and ***Aktiffvate*** will simply be flushed out) or the day after each session. It is advised that the patient should be fasting before the sessions except for liquids. It is also best to start the sessions in the morning, in order to hopefully avoid interrupting their sleep at night.

For any of the sessions, advise the patients to have some type of liquid electrolyte replenisher on hand, e.g., Gatorade, Coconut water, etc. to replace the diarrheal losses. Without this, typical dehydration symptoms can ensue, such as headaches, leg cramps, dizziness, weakness, etc. Finally, for the liquid Golden Sunrise Nutraceutical herbal products in the first two (2) sessions of each protocol, direct the patient to pour the contents into a drinking glass instead of drinking it directly from the original one fluid ounce (1–fl.oz.) bottle provided. The liquid herbs must be drunk as quickly as possible, like a shot of liquor, without sniffing it or holding it in the mouth at all. Some people may need to be advised to pinch their nostrils to avoid smelling the herbal products as they swallow them. Have a glass or bottle of water on hand to wash it down immediately. Water, not milk or juices, generally helps better for the after–taste. Be careful to avoid too much water, because becoming water-logged can cause nausea as well. If the throat is very irritated, sucking on honey or syrup to coat the throat afterwards can be helpful. There have been few problems encountered in this process. However, some patients who have asthma

have experienced bronchospasm. Taking 1–2 puffs of their rescue inhaler before swallowing the liquid herbs has avoided or minimized this reaction.

The other Golden Sunrise Nutraceutical herbal products, most of which are given after the initial five (5) sessions of treatment, are included in the price of the ***METABOLIC Plan of Care*** protocol. They include ***AnterFeeron*** (the ***AnterFeeron-I*** and ***AnterFeeron-II*** must be given in the same session), ***C_RProtein***, ***HyProtein***, and ***LyProtein***. They can be given in any order after the first five (5) sessions every 2–4 weeks. Many of them can also cause the same flushing response as the Golden Sunrise Nutraceutical herbal products used in the initial five (5) sessions. These are designed primarily to improve nourishing and building the immune system.

Lastly, it must be said, that the ability to heal by any discipline is influenced by numerous factors. This is no different with the healing properties of these herbs. Crucial factors, some of which are stress, diet, exercise, socioeconomic and psychological conditions, as well as family / friend support, affect the response to any healing modality for each person. Addressing these are required to help enhance the degree of healing that can occur for each person.

4.1 Administration and Dosage of *IMUNSTEM* and *AKTIFFVATE*

Upon the first visit it is suggested that once the medical evaluation of the patient is completed and the medical staff deems it appropriate, then patients will receive ½ – ¾ of a dropperful of ***ImunStem*** and ***Aktiffvate*** 1–4 times a day. The medical staff should monitor the patient for at least ten (10) minutes to help with any effects that might need other medical attention. For example, ***ImunStem*** can open and improve blood flow throughout the body and the patient might experience a feeling of warmth and begin having nasal mucus discharge. After ten (10) minutes if the patient is stable, the ¾ dropperful of ***Aktiffvate*** should be administered with similar monitoring.

***ImunStem* and *Aktiffvate* are liquid form:**

Product	Dose	Dose Size of a Dropper	Dose Per day
ImunStem	1 ml	½ - ¾	1–4
Aktiffvate	1 ml	½ - ¾	1–4

If the patient has a sensitivity of the mouth and / or throat, then the administration in one (1) teaspoonful of yogurt or filling empty gelatin capsules and swallowing them can be done.

4.2 Administration and Dosage of *DETOXHERBS*

Take one fluid ounce (1 fl.oz.) of ***DetoxHerb–1***. Medical staff should monitor the patient for forty-five (45) minutes to one (1) hour following ingestion of ***DetoxHerb–1***. Next take one fluid ounce (1 fl.oz.) of ***DetoxHerb–2***, the same dosage. Again medical staff should monitor the patient for thirty (30) minutes following ingestion of ***DetoxHerb–2***.

***DetoxHerb–1* and *DetoxHerb–2* are liquid form:**

Product	Dose
DetoxHerb-1	1 fl.oz.
DetoxHerb-2	1 fl.oz.

Take twenty-five (25) capsules of ***DetoxHerb–PI***, ideally within fifteen (15) minutes. After fifteen (15) minutes take, twenty (25) capsules of ***DetoxHerb–NR***, ideally within fifteen (15) minutes.

***DetoxHerb–PI* and *DetoxHerb–NR* are powder form:**

Product	Dose
DetoxHerb-PI	25 capsules
DetoxHerb-NR	25 capsules

4.3 Administration and Dosage of *ANTERFEERONS*

Take one fluid ounce (1 fl.oz.) of ***AnterFeeron–1***. Then in forty-five (45) minutes to one (1) hour following ingestion of ***AnterFeeron–1***, take one fluid ounce (1 fl.oz.) of ***AnterFeeron–2***, administered in the same dose.

***AnterFeeron–1* and *AnterFeeron–2* are liquid form:**

Product	Dose
AnterFeeron-1	1 fl.oz.
AnterFeeron-2	1 fl.oz.

4.4 Administration and Dosage of *C_RPROTEIN*

Take one fluid ounce (1 fl.oz.) of ***C_RProtein***. Medical staff may monitor the patient for forty-five (45) minutes to one (1) hour following ingestion of ***C_RProtein***.

***C_RProtein* is liquid form:**

Product	Dose
C_RProtein	1 fl.oz.

4.5 Administration and Dosage of *HYPROTEINS*

Take twenty-four (24) capsules of ***HyProtein–1*** (ideally take each dose of twenty-four (24) capsules within a fifteen (15) minute space of time). After thirty (30) minutes, take twenty-four (24) capsules of ***HyProtein–2***. After thirty (30) minutes, take twenty-four (24) capsules of ***HyProtein–3***. After five (5) hours, take twenty-four (24) capsules of ***HyProtein–4*** (½ of the bottle). After another five (5) hours, take the last twenty-four (24) capsules of ***HyProtein–4***.

***HyProteins* are powder form:**

Product	Dose
HyProtein-1	24 capsules
HyProtein-2	24 capsules
HyProtein-3	24 capsules

HyProtein-4	24 capsules

4.6 Administration and Dosage of *LYPROTEINS*

Take twenty-five (25) capsules of ***LyProtein***, ideally within fifteen (15) minutes. After fifteen (15) minutes, take the last twenty-five (25) capsules of ***LyProtein***, ideally within fifteen (15) minutes.

***LyProtein* is powder form:**

Product	Dose
LyProtein	50 capsules

4.7 Treatment Interval and Duration of *METABOLIC Plan of Care*

The basic treatment recommended by Golden Sunrise Nutraceutical for cancer requires five (5) initial sessions of herbal (botanical) products (usually including ***DetoxHerb–1***, ***DetoxHerb–2***, ***DetoxHerb–PI***, ***DetoxHerb–NR***, ***AnterFeeron–1***, and ***AnterFeeron–2***). These are recommended to be taken every 2–4 weeks apart. Then additional sessions (up to four (4) or five (5) more) will be included, if warranted by the patient's response and condition, with other high quality herbal products (some of which include ***C_RProtein***, ***HyProteins***, and ***LyProtein***). These are also recommended to be taken every 2–4 weeks apart.

The ***METABOLIC Plan of Care*** is designed to modify or reverse the abnormal metabolic process at the cellular level which are the source of all of our diseases. The ***METABOLIC Plan of Care*** is also designed as a preventative plan of care to arrest or reverse the metabolic abnormalities at the cellular level leading to the development of cancer cells. Then every 6–12 months a detoxification Golden Sunrise Nutraceutical herbal treatment session will be recommended as a preventative for different disease pathways as well as a prevention for cancer emergence. ***ImunStem*** and ***Aktiffvate*** will be continued indefinitely, but tapered to a lower dose, for example, ¼ dropperful of each every other day.

5.0 WARNING AND PRECAUTIONS

ADMINISTRATION OF ***IMUNSTEM***, ***AKTIFFVATE***, ***DETOXHERBS***, ***ANTERFEERONS***, ***C_RPROTEIN***, ***HYPROTEINS*** AND ***LYPROTEIN*** SHOULD ALWAYS BE UNDER THE SUPERVISION OF A PHYSICIAN. RECOMMENDATION FOR GOLDEN SUNRISE NUTRACEUTICAL ***METABOLIC PLAN OF CARE*** IS BASED ON MEDICAL EVALUATION OF THE PATIENT, AND LABORATORY RESULTS. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

6.0 THERAPEUTIC RESPONSE

6.1 Expected Response of *DetoxHerbs, AnterFeerons, C_RProtein, HyProteins, and LyProtein*

The ***METABOLIC Plan of Care*** process can promote the body's natural cleansing process which usually will include responses such as nausea, vomiting, diarrhea, and mucus

discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, such as headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***METABOLIC Plan of Care***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

6.2 Adverse Sensitivity Response of *ImunStem and Aktiffvate*

- ***ImunStem*** and ***Aktiffvate*** can cause severe allergic skin rashes.
- Vomiting.
- In rare circumstances an adverse sensitivity response in the mouth, such as mild blisters, have occurred.
- A burning sensation in the throat in the beginning of oral treatment may occur, but it subsides. If the burning sensation persists, gelatin capsules used for administration, may be substituted as an alternative.

7.0 CLINICAL PHARMACOLOGY

7.1 Mechanism of Action

Golden Sunrise Nutraceutical produces herbal (botanical) products which help to regenerate the cell and promote the cellular metabolism to return to homeostasis in the human body.

It is postulated that in arresting abnormal cellular mutation, the precursors for normal and enhanced cellular regeneration and cellular division can be accelerated in relation to the selective existing disease pathology. It is therefore theorized that the combination of the body's thermal energy, particularly during variance mutation and inflammatory processes, potentiates the self-propelling of molecules by possible passive membrane transportation or passive diffusion of the Golden Sunrise Nutraceutical products intact across all cell membranes. This also includes the blood-brain barrier, which allows its efficacy and activity for the central nervous system.

Golden Sunrise Nutraceutical products possess a bipolarity and a lipophilicity that facilitates molecular diffusion through various permeable and selective membranes. In-vivo studies on test subjects have indicated that the cell membrane integrity remains intact and is not disrupted or destroyed in the process of assimilating into the cell, thus ensuring long-term effectiveness.

The technology developed by Golden Sunrise Nutraceutical is the key for the various herbs' effectiveness on the immune system and cellular metabolism. They have immune-stimulating properties. In-vivo studies on treated patients demonstrate increasing repair, before, during and after chemotherapy drugs, prescription drugs, toxic exposure and

phagocytic activity and synthesis of helper cell function. Golden Sunrise Nutraceutical products have shown to transform Deoxyribonucleic Acid / Ribonucleic Acid (DNA / RNA) chemical induced damage. These herbs have a variety of effects including anti-oxidant activity and anti-inflammatory properties.

Golden Sunrise Nutraceutical products can play an integral role in hypothalamic activity, easing both parasympathetic and sympathetic nervous systems towards a state of homeostasis. For example, blood pressure level is directly linked to the sympathetic nervous system and the normalizing of blood pressure levels exhibited following administration of Golden Sunrise Nutraceutical products are compatible with the stabilization of the sympathetic nervous system activity. Golden Sunrise Nutraceutical products reduces inflammation by affecting immune responsiveness through neuroendocrine factors. Improvement of balance problems, a side effect of some chemotherapies, by Golden Sunrise Nutraceutical products is thought to be from improvement of vestibular function. Golden Sunrise Nutraceutical products have affected bone metabolism by demonstrating improved bone density in patients with osteoporotic bone. Numbers based on densitometry have shown a reversal in L1–L4 from –3.6% to 3.4% in 1–year.

7.2 Pharmacokinetics

Golden Sunrise Nutraceutical products are readily absorbed into soft tissue when taken as an oral dose. This is accomplished because Golden Sunrise Nutraceutical products readily passes through membrane tissue by passive diffusion.

The Golden Sunrise Nutraceutical dietary supplements are metabolized by the body to more hydrophilic products that are excreted in the urine and feces.

8.0 RESULTS OF PATIENTS AFTER TREATMENT

Please download at www.goldensunrisenutraceutical.com under "**TREATMENT**" and click "***Insulin Resistance Cellular Restorative Results***".

9.0 STORAGE, HANDLING, AND PRODUCTS

9.1 Storage and Stability

STORAGE: Store materials at controlled room temperature 20°C (68°F).

STABILITY: ***METABOLIC Plan of Care*** is chemically stable for two (2) years at room temperature. Do not freeze.

9.2 Product Classification

Dietary Supplement.

10.0 ATTACHMENT LABELS

DetoxHerb–1, ***DetoxHerb–2***, ***DetoxHerb–NR***, ***DetoxHerb–PI***, ***AnterFeeron–1***, ***AnterFeeron–2***, ***CRProtein***, ***HyProtein–1***, ***HyProtein–2***, ***HyProtein–3***, ***HyProtein–4***, ***LyProtein***, ***ImunStem***, and ***Aktiffvate***

11.0 HOW SUPPLIED

11.1 Packaging

PRODUCT	CONTAINER CONTENT	NET CONTENT
ImunStem	3 bottles	1 fl.oz. Liquid
Aktiffvate	3 bottles	1 fl.oz. Liquid
DetoxHerb-1	2 bottles	1 fl.oz. Liquid
DetoxHerb-2	2 bottles	1 fl.oz. Liquid
DetoxHerb-PI	1 bottles	25 capsules Powder
DetoxHerb-NR	1 bottles	25 capsules Powder
AnterFeeron-1	2 bottles	1 fl.oz. Liquid
AnterFeeron-2	2 bottles	1 fl.oz. Liquid
LyProtein	1 bottles	50 capsules Powder
C_RProtein	1 bottles	1 fl.oz. Liquid
HyProtein-1	1 bottles	24 capsules Powder
HyProtein-2	1 bottles	24 capsules Powder
HyProtein-3	1 bottles	24 capsules Powder
HyProtein-4	1 bottles	48 capsules Powder

METABOLIC Plan of Care

CELLULAR THERAPY

DetoxHerb–1

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Poke weed	100mg	**
Graviola	65mg	**
Turmeric	17mg	**
** Daily Value (DV) not established.		

Other Ingredients: solvents, organic compounds, Selfheal, Chuchuhuasi, Yucca, Cat's claw, and Black pepper.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"

"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***DetoxHerb–1*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***DetoxHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***DetoxHerb–1*** into a glass cup and swallow entire contents.

Dosage: Take one fluid ounce (1 fl.oz.)

DetoxHerb–1 dietary supplement may support immunity, improve overall health for the human body and maintain good well–being.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***DetoxHerb–1***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

DetoxHerb–2

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Olive leaf	110mg	**
Papaya leaf	70mg	**
Vinca	120mg	**
** Daily Value (DV) not established.		

Other Ingredients: Chuchuhuasi, Cat's claw, and Turmeric.

STRUCTURE FUNCTION

"Promote Bowel Movements"

The ***DetoxHerb–2*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***DetoxHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***DetoxHerb–2*** into a glass cup and swallow entire contents.

Dosage: Take one fluid ounce (1 fl.oz.)

DetoxHerb–2 dietary supplement may help promote bowel movements.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***DetoxHerb–2***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

DetoxHerb–PI

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 25 capsules serving		
Amount Per Serving		**%DV**
Bilberry	40mg	**
Graviola	120mg	**
Goldenseal	50mg	**
** Daily Value (DV) not established.		

Other ingredients: Chuchuhuasi, Cayenne, Maca, and Turmeric.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***DetoxHerb–PI*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***DetoxHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-five (25) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***DetoxHerb–PI***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

DetoxHerb–NR

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 25 capsules serving		
Amount Per Serving		**%DV**
Gotu kola	60mg	**
Foti	35mg	**
Vinca	45mg	**
** Daily Value (DV) not established.		

Other ingredients: Green tea, Rhodiola, Yucca, and Turmeric.

STRUCTURE FUNCTION

"Promote Bowel Movements"

The ***DetoxHerb–NR*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***DetoxHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-five (25) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***DetoxHerb–NR***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

AnterFeeron–1

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Bilberry leaf	40mg	**
Graviola	120mg	**
Goldenseal	80mg	**
** Daily Value (DV) not established.		

Other Ingredients: solvents, organic compounds, Chuchuhuasi, Cayenne, Maca, and Turmeric.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint Health and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***AnterFeeron–1*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***AnterFeeron***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***AnterFeeron–1*** into a glass cup and swallow entire contents.

Dosage: Take one fluid ounce (1 fl.oz.)

AnterFeeron–1 dietary supplement may support immunity, improve overall health for the human body and maintain good well–being.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***AnterFeeron–1***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

AnterFeeron–2

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Astragalus	20mg	**
Reishi	95mg	**
Mistletoe	45mg	**
** Daily Value (DV) not established.		

Other Ingredients: Cat's claw, organic compounds, Echinacea, and Cordyceps.

STRUCTURE FUNCTION

"Promote Bowel Movements"

The ***AnterFeeron–2*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***AnterFeeron***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***AnterFeeron–2*** into a glass cup and swallow entire contents.

Dosage: Take one fluid ounce (1 fl.oz.)

AnterFeeron–2 dietary supplement may support immunity, improve overall health for the human body and maintain good well–being.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***AnterFeeron–2***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

C_RProtein

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Cat's claw	35mg	**
Selfheal	10mg	**
Rosemary	20mg	**
** Daily Value (DV) not established.		

Other Ingredients: Turmeric.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint Health and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***C_RProtein*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***C_RProtein***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***C_RProtein*** into a glass cup and swallow entire contents.

Dosage: Take one fluid ounce (1 fl.oz.)

C_RProtein dietary supplement may support immunity, improve overall health for the human body and maintain good well–being.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***C_RProtein***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

HyProtein–1

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 24 capsules serving		
Amount Per Serving		**%DV**
Astragalus	95mg	**
Oregano	40mg	**
Cat's claw	70mg	**
** Daily Value (DV) not established.		

Other ingredients: Olive leaf and Blood root.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***HyProtein–1*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***HyProtein***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-four (24) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***HyProtein–1***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

HyProtein–2

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 24 capsules serving		
Amount Per Serving		**%DV**
Blood root	55mg	**
Reishi	75mg	**
Green tea	40mg	**
** Daily Value (DV) not established.		

Other ingredients: Turmeric, Pokeweed, and Garlic.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***HyProtein–2*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***HyProtein***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-four (24) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***HyProtein–2***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

HyProtein–3

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 24 capsules serving		
Amount Per Serving		**%DV**
Ashwagandha	45mg	**
Garlic	60mg	**
Turmeric	30mg	**
** Daily Value (DV) not established.		

Other ingredients: Ginkgo, Green tea, and Catuaba bark.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***HyProtein–3*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***HyProtein***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-four (24) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***HyProtein–3***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

HyProtein–4

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 48 capsules serving		
Amount Per Serving		**%DV**
St. John's wort	50mg	**
Reishi	30mg	**
Garlic	25mg	**
** Daily Value (DV) not established.		

Other ingredients: Kudzu, Goldenseal, and Licorice root.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***HyProtein–4*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***HyProtein***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-four (24) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***HyProtein–4***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

METABOLIC Plan of Care

CELLULAR THERAPY

LyProtein

Dietary Supplement

WARNING

Keep out of reach of children

do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 50 capsules serving		
Amount Per Serving		**%DV**
Horse chestnut	25mg	**
Garlic	40mg	**
Turmeric	50mg	**
** Daily Value (DV) not established.		

Other ingredients: Sea cucumber, Astragalus, Bilberry, Olive leaf, and St. John's wort.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***LyProtein*** has no side-effects. It will promote the body's natural cleansing process which may include purging responses such as nausea, diarrhea, vomiting and mucus discharges. Other possible symptoms a person can experience may depend on the person's previous health issues, which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath. These symptoms are only temporary at the time that the patient is being treated with ***LyProtein***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-five (25) capsules, ideally within fifteen (15) minutes.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***LyProtein***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

ImunStem®

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (0.50ml) (491.50mg)		
Serving Per Container: 25 servings		
Amount Per Serving		**%DV**
Olive Leaf extract	260mg	**
Yarrow extract	52mg	**
Rosemary extract	63mg	**
** Daily Value (DV) not established.		

Other Ingredients: Organic compounds and solvents, monoterpene, Cassia oil, and Yucca.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"

ADVERSE ACTIONS
* In rare circumstances an adverse reaction in the mouth such as "mild blisters" have occurred.
* A burning sensation in the throat in the beginning of oral treatment may occur, but subsides. If the burning sensation persists, filling gelatin capsules and swallowing may be substituted as an alternative.
* Vomiting.
* Yarrow flowers can cause severe allergic skin rashes.

Shake bottle well before using and use dropper to place ½ – ¾ dropperful of ***ImunStem*** under the tongue. Leave under the tongue for approximately forty (40) seconds and then swallow with a drink of water.

Dosage: Take ½ – ¾ dropperful, 1–4 times a day, as frequently as every 1–3 hours.

ImunStem dietary supplement may support immunity, improve overall health for the human body and maintain good well–being.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***ImunStem***, please consult your doctor or call the product hot line in U.S. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Aktiffvate®

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (0.50ml) (491.50mg)		
Serving Per Container: 25 servings		
Amount Per Serving		**%DV**
Turmeric extract	175mg	**
Cayenne extract	40mg	**
Eucalyptus extract	20mg	**
** Daily Value (DV) not established.		

Other Ingredients: Wintergreen, solvents, organic compounds, Yucca, and Olive leaf.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"
"Reduces Stress and Frustration"

ADVERSE ACTIONS
* In rare circumstances an adverse reaction in the mouth such as "mild blisters" have occurred.
* A burning sensation in the throat in the beginning of oral treatment may occur, but subsides. If the burning sensation persists, filling gelatin capsules and swallowing may be substituted as an alternative.
* Vomiting.

Shake bottle well before using and use dropper to place ½ – ¾ dropperful of ***Aktiffvate*** under the tongue. Leave under the tongue for approximately forty (40) seconds and then swallow with a drink of water.

Dosage: Take ½ – ¾ of a dropperful, 1–4 times a day, as frequently as every 1–3 hours.

Aktiffvate dietary supplement may support immunity, improve overall health for the human body and maintain good well–being.

WARNING: Not recommended for use by pregnant or nursing women. Should you have any questions regarding the use of ***Aktiffvate***, please consult your doctor or call the product hot line in U.S. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Insulin Resistance Cellular Restorative Results

With Our 100% Herbal Treatment

Golden Sunrise Nutraceutical, Inc.
P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

Revised: 04/2019

Golden Sunrise NUTRACEUTICAL
P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

TITLE

Insulin Resistance Cellular Restorative Results

PRODUCT

DetoxHerb-1, DetoxHerb-2, DetoxHerb-PI, DetoxHerb-NR, AnterFeeron-1, AnterFeeron-2, C_RProtein, HyProtein-1, HyProtein-2, HyProtein-3, HyProtein-4, LyProtein, ImunStem, and Aktiffvate

DATE

April 22, 2019

P.O. Box 510
PORTERVILLE, CA 93258 * U.S.A.
Phone No.: 1.559.781.0658 Fax No.: 1.559.615.1268

INSULIN RESISTANCE CELLULAR RESTORATIVE RESULTS

THERAPIES	SIDE-EFFECTS	QUALITY OF LIFE	RECOMMENDED TREATMENT	COST (US$)
METABOLIC Plan fo Care	None	Good Well-being	Golden Sunrise Nutraceutical ***METABOLIC Plan of Care***	170,000 - 200,000
No Treatments	----------	----------	No Treatments	----------

RESULTS OF PATIENTS AFTER TREATMENT with GOLDEN SUNRISE NUTRACEUTICAL "METABOLIC Plan of Care"

Approximately 99%-of-patients treated with Golden Sunrise Nutraceutical's ***DetoxHerbs*** (dietary supplement) found that their quality-of-life improved. These patients were treated with ***DetoxHerbs*** over the course of a few months and up to 6-years.

Physicians noted that implementing Golden Sunrise Nutraceutical's ***METABOLIC Plan of Care***, with Golden Sunrise Nutraceutical's products produced a significant response in 99% of their patients. A reduction of symptoms in patient's with conditions such as Alzheimer's Disease, Amyotrophic Lateral Sclerosis (ALS), Autoimmune Disorders, Cancer, Constipation, Debilitating Chronic Pain, Diabetes, Epilepsy, Fibromyalgia, Fragile-X Syndrome, Hemostasis (less blood to be lost), Hypertention, Menopause, Multiple Sclerosis (MS), Obesity, Osteopenia, Parkinson's Disease, Prostate, Schizophrenia, Stroke, Thalassemia, Viral Illesses and more.

The significant response observed by physicians and patients was a decrease in glucose levels, with no reported side-effects, such as dizziness or disorientation. Some have shown a drop in their blood sugar levels from 400-mg/dL to 50-mg/dL, and remained fine without the need for sugars. Patients also reported significant improvements in mood and skill development during treatments.

Patients being treated with Golden Sunrise Nutraceutical ***METABOLIC Plan of Care*** have shown dramatic improvements in bone density for patients. Numbers based on densitometry have shown a reversal in L1-L4 from -3.6% to 3.4% in 1-year.

Golden Sunrise NUTRACEUTICAL

Insulin Resistance Cellular Restorative Results

INSULIN RESISTANCE CELLULAR RESTORATIVE RESULTS

(#)	NAME *and* AGE	PATIENTS BEFORE TREATMENT *of* DIAGNOSIS	RESULTS OF PATIENTS AFTER TREATMENT *with* GOLDEN SUNRISE NUTRACEUTICAL *Metabolic Plane of Care*
(1)	N. O., 22-years-old	Type I Diabetes Mellitus diagnosed February 2012 Requires insulin refill for the pump every 30-days Requires constant use of the pump Required changing needle insertion site every 3-4-days to avoid infection Poor energy, poor motivation, higher sleep requirement and blood sugars always in the 300-mg/dL to 400-mg/dL	Started GSN* July 2018. Requires insulin refill for the pump every 40-50-days. During the third detoxification treatment the blood sugar dropped from over 400-mg/dL to 50-mg/dL. He felt great energy, no tremors, instead of the usual sense of apprehension, tremors and feeling sick. During the detoxification treatments remains off of the pump for 6-8-hours. Requires changing needle insertion site every 10-14 days and still no signs of infection (redness, swelling, pus), Hgb A1C improved from 9.1% to 8.6% in last 3-months, January – April 2019. Much more energy, outside basketball and sports, more motivation, less sleep requirement.
(2)	S. T., 60-years-old	Migraines and Osteopenia Migraine headaches and general back ache	Started GSN* July 2017. No more Migraines. ***Bone Density L1-L4:*** +3.4%{0.886 g/cm2, (59-year-old) 06/26/2018 -3.6%{0.857 g/cm2, (58-year-old) 07/05/2017 -2.7%{0.889 g/cm2, (54-year-old) 05/03/2013
(3)	E. B., 47-years-old	Multiple Sclerosis DX-2002 Bed bound since 2015	Started GSN* October 04, 2017. By April 04, 2019 able to walk with a lift walker about 30-minutes. By April 19, 2019 he had been off of Topamax medicine for tremors for a few months and reduced Gabapentin 600 mg. 3-times a day to 100-mg. three times a day. Also recently completely off of Oxycontin ER-30mg twice a day and tapered off of Percocet 10/325-three-times a day to Percocet 5/325-½-tablet 1-2-times a day.

*GSN = Golden Sunrise Nutraceutical

INSULIN RESISTANCE CELLULAR RESTORATIVE RESULTS

(#)	NAME *and* AGE	PATIENTS BEFORE TREATMENT *of* DIAGNOSIS	RESULTS OF PATIENTS AFTER TREATMENT *with* GOLDEN SUNRISE NUTRACEUTICAL *Metabolic Plane of Care*
(4)	J. G., 32-years-old	Fibromyalgia Symptoms: Diffuse chronic muscle and tendon pain, fatigue	Start ImunStem/Aktiffvate on May 2017. Muscle and Tendon pain improved tremendously, avoided need for narcotic pain medication.
(5)	S. M., 66-years-old	Prostatic Hypertrophy 4-5-times up at night to urinate, slow urine stream On Tamsulosin 0.4-mg every day.	Started GSN* December 2016. Stopped Tamsulosin. No problems with urination.
(6)	D. M., 63-years-old	Severe right knee Osteoarthritis Chronic use of Motrin, Naprosyn, etc. and muscle relaxers, Flexeril, etc. Knee surgery scheduled August 2017	Started GSN* May 2017. Cancelled knee surgery. No more use of anti-inflammatory medications or muscle relaxers. Able to climb stars and hike without arthritis pain.
(7)	R. W., 54-years-old	HTN High Blood Pressure On Lisinopril 10-mg/day and Bystolic every day	Started GSN* on November 08, 2018. Stopped all blood pressure medication by December 07, 2018.
(8)	L. G., 52-years-old	Lyme Disease Recurrent muscle aches and pains, chronic insomnia, chronic headaches on 30-pills a day	Started GSN* October 07, 2018. Muscle aches and pains improved. Insomnia totally resolved. Frequency of headaches greatly diminished. Overall sense of well-being, fatigue some improvement. Off all medication.
(9)	C. A., 63-years-old	Alzheimer's and Dementia since 2016 Short term memory loss Disoriented to time and place Difficulty following conversation Confusion	Started GSN* August 11, 2018. Within 3-4-days noticeable improvement in comprehension. Improved backaches and headaches. Stopped Aricept and Elavil anti-depressant and Methocarbamol muscle relaxer. Decrease Celexa 20 mg. anti-depressant from 1 1/2 tablets per day to ½ tablet per day.
(10)	T. T., 48-years-old	Psychotic Disorder Auditory and visual hallucinations	Since on GSN* he has stopped all of his anti-psychotic medications and has minimal auditory hallucinations.

*GSN = Golden Sunrise Nutraceutical

INSULIN RESISTANCE CELLULAR RESTORATIVE RESULTS

(#)	NAME *and* AGE	PATIENTS BEFORE TREATMENT *of* DIAGNOSIS	RESULTS OF PATIENTS AFTER TREATMENT *with* GOLDEN SUNRISE NUTRACEUTICAL *Metabolic Plane of Care*
(11)	J. A. 2-years-old	Autism, Severe Diagnosed November 30, 2016 Hyperactive Running around, very poor attention span Poor eye contact Poor Appetite Insomnia Avoid personal contact, hugging	GSN* November 2016. Within 3-days of starting GSN he gave eye contact. In 1-week he was making sounds instead of crying. He hugs people now. Sits and watches television shows. Sleeping much better.
(12)	S. W., 68-years-old	Diabetes Mellitus, Peripheral Neuropathy Packed lower legs and feet in ice before bedtime in order to sleep at night	On GSN* no longer need to pack feet in ice to sleep at night.
(13)	R. M., 78-years-old	Parkinson's On several Medications (4-of-them) and not well controlled. Shaking, drooling and falling	GSN* started March of 2015. Only on one medication, much better control. Walking 2-miles with a walker. No falls.

*GSN = Golden Sunrise Nutraceutical

Attachment D

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

TITLE

Investigator's Brochure

PRODUCT

ImunStem, Aktiffvate, and KemoHerbs

DATE

March 25, 2019

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

ABBREVIATION

ABBREVIATION	DEFINITION
DNA	Deoxyribonucleic Acid
FDA	Food and Drug Administration
Golden Sunrise	Golden Sunrise Nutraceutical, Inc.

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

TABLE OF CONTENTS

1.0 INTRODUCTION

The administration of botanical treatments for human health has led to the benefit of cancer treatments from plant based materials. ***ImunStem***, ***Aktiffvate***, and ***KemoHerb*** treatments have been of great value to patients that only use herbal/botanical products for overall health. This has led to improved outcomes for patients. Patients that resist traditional medical therapies and that have used medical therapies that haven't helped in the reduction or elimination of cancer who've been on traditional medical therapies and have suffered from harmful side-effects. Those medical therapies may cause eventual death from soft tissue necrosis overtime.

KemoHerb treatment begins with the use of ***ImunStem*** and ***Aktiffvate*** to improve immune system function then the administration of ***KemoHerbs*** are given to flush the system and arrest the development of the cancer, treatments are continued to support the elimination of cancer cells.

2.0 SUMMARY

By way of introduction, I am Huu S. TIEU, founder of Golden Sunrise and its products. My interest in herbalism started at a young age, and much of my knowledge was passed down through generations, in my family. I was able to elucidate how plant components and plant compounds balance and activate the metabolic synergy of the body.

Chinese is my ancestry, although I was born in Vietnam. Our culture has always been interested in herbal cures, mainly out of necessity. It is the centuries of herbal knowledge passed on to me that has led to the discovery which I am happy to pass on to the American people and all of humanity. My father, grandfather and great-grandfather both specialized in herbal cures, and treated many people in nearby villages.

My father, [redacted] listened to the story of the first emperor of China, and how the Emperor had searched throughout his reign for the "elixir-of-life" and though he never found it, the accidental product of his search was gunpowder.

My great grandfather decided to once again begin the search for the elusive "elixir-of-life" and found in his search that any potion would be complicated. After numerous dead-ends, my great-grandfather concluded that a single cure-all was not realistic, given the complicated structure of the human body and health. It took my great-grandfather his entire life to finally realize this. However, once he came to this realization, he was too aged to continue his search. Knowing that he would not be able to continue, my great-grandfather passed on his conclusions to his son, who then passed them on to his son, and my father passed the conclusions of the generations to me. My father's request was that I continue the search for this elusive "Elixir-of-Life".

I took my father's request to heart and continued the search. Armed with the information handed down to me from my father, and what I had learned on my own I began to break down the needs of people's health, and decided that my main focus should be the immune

system. To strengthen one's immune system, in my opinion, would be the closest I would be able to come to my great-grandfather's dream of an "Elixir-of-Life" and most beneficial for everyone.

My knowledge of herbalism, botany and basic potions initially, were passed down through my family. My father's knowledge was extensive and on more than one occasion he took me out to the natural environment of plants to teach me the differences, and what to look for. A few examples, would be at the age of twelve (12) my father began teaching me how to mix potions, how to isolate different properties of plant material in order to achieve a specific treatment; he also took me on more than one (1) occasion out to natural habitats to learn more about plant, their properties and how to look for what would be most beneficial from that particular plant. My father pointed out and named all of the plants able to withstand the staggering desert heat. He then took me to a Yucca plant and placed a thermometer in the plant. It was one hundred and fifteen (115°) degrees, yet the Yucca did not show any signs of stress or burn marks. The plant was not damaged in any way. My father pointed out that if this plant could withstand such an extreme environment, that there must be some benefit to be held for people. The day ended with my father pointing out all of the properties of each of the plants surrounding us. We then went home and my father had me study all of the plants that we had examined in the desert. A few months later, my father took me to an herb store in San Francisco, California, and explained the technology involved in reducing the properties of the herbs. He also explained how the conclusions that he, and generations before him had arrived at, and how with the introduction of computers, and high-tech software we would be able to expand on their conclusions and receive the maximum benefits. I began in earnest study of plants, their characteristics, their physiology and survivability. Understanding the structural function of the plants, I began experimenting on animals. As I was administering one hundred (100%) percent natural potions, I knew that the chance of a harmful side-effect was minimal.

My research entailed visiting many libraries, internet searches, as well as attending seminars, and speaking with various people in the fields of botany and herbalism. Then years of "Hit and Miss" experiments.

I also studied cells, and how they act/react. I researched the ways that protein, hormones and enzymes interact in the body, and reactions to the cells in the body. I then embarked on a study of DNA and Telomeres to understand whether it was possible to lengthen life through DNA manipulation, and telomere longevity.

I believe that my comprehensive knowledge and understanding of plant physiology, survivability and structure, along with my knowledge of the human body functions has grown through the years. Thus allowing me to incorporate the metabolic synergy of the body to be activated by plant components and plant compounds.

Initially, I was unable to run traditional scientific tests, but rather relied on the technology my father had brought from Vietnam, and conducted studies based on my understanding at the time.

With time I was able to create Golden Sunrise and have very obviously upped my testing methods.

The culmination of my life's work is a variety of Golden Sunrise products, all of which have no known side-effects to date, but my greatest achievement was the FDA approval of ***ImunStem***. My primary product to strengthen the immune system.

ImunStem, ***Aktiffvate***, and the ***KemoHerb*** dietary supplements have been under development for the past thirty (30) years. The initial development was based on assumptions different than treatment therapies used by modern medicine. They start out with a different premise, that is, a disease model. In their model, there are innumerable diseases. With the disease model, modern medicine separated the cell and its function and addresses only the results of a poor functioning cell(s) and not the cell itself. The treatment strategies deal with the symptoms and effects of the disease. This approach awarded many benefits including, not the least of which include, extending longevity and mitigating human suffering. It was a double- edged sword, however, because many of these achievements came with a price, often with side-effects, and in the end, an inability to stop the progression of chronic diseases and the multiplication of drugs to combat these diseases. They have come to a road block, largely because of the limitation of the technology that is used. They were attacking the results and symptoms created by the disease, because their technology only allowed this approach. The ***ImunStem***, ***Aktiffvate***, and ***KemoHerb*** dietary supplement development was based on a different model. In that model there is only one (1) disease. This means that if the cell becomes 'unhealthy', it becomes a ***MALFUNCTIONING*** cell, and a cascade of events occur resulting in illness. The cell and its function must both be addressed at the same time. This required a new technology. It was based on the structural function of plants and the circulatory system of plants. (b) (4) which ultimately lead to the final product. (b) (4) testing confirmed the initial (b) (4) observations to support a theory for human use. This information was then extrapolated to theorize that human tissue would demonstrate a similar characteristic of the condition, to effect repair (and)(or) reversal of the diseased state through the regeneration of cells and cellular structure for the benefit of patient's metabolism, wound, and tissue damage and debilitating diseases. This technology found the method of combining the different herbs in such a way to magnify their properties and treat the cells directly at a cellular level.

Malfunctioning cells must be the focus of attention. There is only one (1) disease in this model: a malfunctioning cell. Cells malfunction for two (2) reasons: toxins and malnutrition. By not addressing nutrition and toxicity of cells in the body, individuals will experience damage on the cellular level that result today in all of the chronic diseases, degenerative disorders, etc., which we are beleaguered with today.

There are many ways to make our bodies deficient and filled with toxins. Toxins are ubiquitous in our environment: pollution of water supplies with addition of bactericides in city water, air pollution from automotive and industrial entities, cosmetics, creams, conditioners, shampoos, hair dyes, make up, pharmaceutical medications, pesticides in food

products, etc. Poor nutrition occurs from starvation or processed foods that lack basic nutrients and contain toxins. Stress and inactivity complicate the picture as well. All the factors that contribute to the problems of a weakened body are staggering. For example, an over-taxed immune system results in body-wide 'inflammation', which perhaps is the best way to describe decreased circulation, accumulation of metabolic waste such as radicals, acid-base imbalance, localized oxygen deprivation, impaired energy production by the cells, and the list goes on. These all lead to unhealthy tissues, i.e. leaky gut problems, malabsorption, autoimmune reactions, cancer, etc. Dr. Otto Heinrich WARBURG, Nobel Prizes & Laureate, 1931, established that cancer cells derive their energy by fermentation chemical reactions and thrive in low oxygen environment (as opposed to healthy cells which require oxygen for their energy). The corollary of this is the high demand for glucose by cancer cells.

Golden Sunrise dietary supplements have established their safe and efficacy in helping to reverse, modify, or heal ***Serious or Life-threatening*** conditions. They cause release of toxins out of the cells and at the same time the herbs supply the essential nutrients which the cells have been starving for. These nutrients serve as building blocks allowing the cells to repair and rejuvenate themselves and return the cells to perform the functions they were intended to perform.

Foreign patient treatments using Golden Sunrise products. Patients have been treated in the counties of Cambodia 2-cancer-patients, China 2-cancer-patients, and Mexico 5-cancer-ptients have shown improved quality-of-life.

The **Attachment 3.1 Cancer Survival Rate Results** shows the US patients treated with only Golden Sunrise products. Other patients treated with traditional cancer treatments such as chemotherapy, radiotherapy, and surgery in addition to Golden Sunrise products have shown an improved quality-of –life.

3.0 ATTACHMENT

3.1 • **Cancer Survival Rate Results**

3.2 • **Aktiffvate Label**
- **ImunStem Label**
- **KemoHerb-1 Label**
- **KemoHerb-2 Label**
- **KemoHerb-PI Label**
- **KemoHerb-NR Label**

4.0 REFERENCES

• The Warburg effect in tumor progression: Mitochondrial oxidative metabolism as an anti-metastasis mechanism.

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

INVESTIGATOR'S BROCHURE

ImunStem, Aktiffvate, and KemoHerbs

END

March 25, 2019

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

ATTACHMENT

3.1 Cancer Survival Rate Results

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

TITLE

CANCER SURVIAL RATE RESULTS

COMPLETE ON

March 18, 2019

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

ATTACHMENT

3.2 Aktiffvate, ImunStem, KemoHerb-1, KemoHerb-2, KemoHerb-PI, and KemoHerb-NR

Aktiffvate®

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (0.50ml) (491.50mg)		
Serving Per Container: 25 serving		
Amount Per Serving		**%DV**
Turmeric extract	175mg	**
Cayenne extract	40mg	**
Eucalyptus extract	20mg	**
** Daily Value (DV) not established.		

Other Ingredients: Wintergreen, solvents, organic compounds, fatty acids, Yucca extract and Olive leaf extract.

STRUCTURE FUNCTION

"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"
"Reduces Stress and Frustration"

ADVERSE ACTIONS

* In rare circumstances an adverse reaction in the month such as "mild blisters" have occurred.
* A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a beneficial response.
* Vomiting.

Administration: Shake bottle well before using and use dropper to place ½ to ¾ quarter of a dropper of ***Aktiffvate*** under tongue. Leave under tongue for approx forty (40) seconds and then drink water.

Dosage: Take ½ to ¾ quarter of a dropper, 1–4 times a day, between one (1) and three (3) hours.

Aktiffvate dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***Aktiffvate***, please consult your doctor or call the product hot line in U.S. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Manufactured by: **Golden Sunrise Nutraceutical Inc.**
P.O. Box 510
PORTERVILLE, CA 93257 * U.S.A.

ImunStem®

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (0.50ml) (491.50mg)		
Serving Per Container: 59 serving		
Amount Per Serving		**%DV**
Olive Leaf extract	260mg	**
Yarrow extract	52mg	**
Rosemary extract	63mg	**
** Daily Value (DV) not established.		

Other Ingredients: Organic compounds and solvents, monoterpene, fatty acid, cassia oil and yucca.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps Provide Temporary Relief for People in Serious or Life-threatening Situation"
"Helps You Relax"

ADVERSE ACTIONS
* In rare circumstances an adverse reaction in the month such as "mild blisters" have occurred.
* A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a beneficial response.
* Vomiting.
* Yarrow flowers can cause severe allergic skin rashes.

Administration: Shake bottle well before using and use dropper to place zero point fifty (0.50ml) of ***ImunStem*** under tongue. Leave under tongue for approx forty (40) seconds and then drink water.

Dosage: Take 0.50 – 0.75ml, 1 – 4 times a day, between one (1) and three (3) hours.

ImunStem dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

Golden Sunrise NUTRACEUTICAL

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***ImunStem***, please consult your doctor or call the product hot line in U.S. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Manufactured by: **Golden Sunrise Nutraceutical Inc.**
P.O. Box 510
PORTERVILLE, CA 93258 * U.S.A.
Patent No.: 3/654,620

ImunStem is a Registered Trademark of Golden Sunrise Pharmaceutical Inc.

KemoHerb-1

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Bilberry leaf	40mg	**
Graviola extract	120mg	**
Goldenseal extract	80mg	**
** Daily Value (DV) not established.		

Other Ingredients: solvents, organic compounds, Chuchuhuasi extract, Cayenne, Maca and Turmeric.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint Health and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"
"Reduces Stress and Frustration"

The ***KemoHerb-1*** has no toxic side-effects. It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, mucus discharges, other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***KemoHerb-1*** into a glass cup and swallow entire contents.

Dosage: Take one (1) fl.oz.

KemoHerb-1 dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***KemoHerb-1***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 510
PORTERVILLE, CA 93258 * U.S.A.

KemoHerb-2

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Olive leaf extract	84mg	**
Papaya leaf extract	112mg	**
Vinca extract	110mg	**
** Daily Value (DV) not established.		

Other Ingredients: solvents, organic compounds, Chuchuhuasi extract, Cat's claw and Turmeric.

STRUCTURE FUNCTION
"Promote Bowel Movements"

The ***KemoHerb-2*** has no toxic side effects. It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, mucus discharges, other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***KemoHerb-2*** into a glass cup and swallow entire contents.

Dosage: Take one (1) fl.oz.

KemoHerb-2 dietary supplement may help promote bowel movements.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***KemoHerb-2***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Manufactured by: **Golden Sunrise Nutraceutical Incorporation**
P.O. Box 510
PORTERVILLE, CA 93258 * U.S.A.

KemoHerb-PI

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS **Serving Size:** 350mg per capsule **Serving Per Container:** 25 capsules serving		
Amount Per Serving		**%DV**
Bilberry	40mg	**
Graviola	120mg	**
Goldenseal	50mg	**
** Daily Value (DV) not established.		

Other ingredients: Chuchuhuasi, Cayenne, Maca, and Turmeric.

STRUCTURE FUNCTION
"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

The ***KemoHerb-PI*** has no toxic side-effects. It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, mucus discharges, other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-four (24) capsules.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***KemoHerb-PI***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 510
PORTERVILLE, CA 93258 * U.S.A.

KemoHerb-NR

Dietary Supplement

WARNING
Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: 350mg per capsule		
Serving Per Container: 25 capsules serving		
Amount Per Serving		**%DV**
Gotu kola	60mg	**
Foti	35mg	**
Vinca	45mg	**
** Daily Value (DV) not established.		

Other ingredients: Green tea, Rhodiola, Yucca, and Turmeric.

STRUCTURE FUNCTION
"Promote Bowel Movements"

The ***KemoHerb-NR*** has no toxic side-effects. It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, mucus discharges, other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Dosage: Take twenty-four (24) capsules.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***KemoHerb-NR***, please consult your doctor or call the product hot line in U.S.A. at 1.559.781.0658 or 1.559.361.0097. Keep out of reach of children. To be kept in a dry and cool place.

* These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Golden Sunrise NUTRACEUTICAL

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 510
PORTERVILLE, CA 93258 * U.S.A.

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

TITLE

Investigator's Brochure

PRODUCT

ImunStem, Aktiffvate, and KemoHerbs

DATE

March 25, 2019

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

ABBREVIATION

ABBREVIATION	DEFINITION
DNA	Deoxyribonucleic Acid
FDA	Food and Drug Administration
Golden Sunrise	Golden Sunrise Nutraceutical, Inc.

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

TABLE OF CONTENTS

1.0 INTRODUCTION

The administration of botanical treatments for human health has led to the benefit of cancer treatments from plant based materials. ***ImunStem***, ***Aktiffvate***, and ***KemoHerb*** treatments have been of great value to patients that only use herbal/botanical products for overall health. This has led to improved outcomes for patients. Patients that resist traditional medical therapies and that have used medical therapies that haven't helped in the reduction or elimination of cancer who've been on traditional medical therapies and have suffered from harmful side-effects. Those medical therapies may cause eventual death from soft tissue necrosis overtime.

KemoHerb treatment begins with the use of ***ImunStem*** and ***Aktiffvate*** to improve immune system function then the administration of ***KemoHerbs*** are given to flush the system and arrest the development of the cancer, treatments are continued to support the elimination of cancer cells.

2.0 SUMMARY

By way of introduction, I am Huu S. TIEU, founder of Golden Sunrise and its products. My interest in herbalism started at a young age, and much of my knowledge was passed down through generations, in my family. I was able to elucidate how plant components and plant compounds balance and activate the metabolic synergy of the body.

Chinese is my ancestry, although I was born in Vietnam. Our culture has always been interested in herbal cures, mainly out of necessity. It is the centuries of herbal knowledge passed on to me that has led to the discovery which I am happy to pass on to the American people and all of humanity. My father, grandfather and great-grandfather both specialized in herbal cures, and treated many people in nearby villages.

My father, [redacted] listened to the story of the first emperor of China, and how the Emperor had searched throughout his reign for the "elixir-of-life" and though he never found it, the accidental product of his search was gunpowder.

My great grandfather decided to once again begin the search for the elusive "elixir-of-life" and found in his search that any potion would be complicated. After numerous dead-ends, my great-grandfather concluded that a single cure-all was not realistic, given the complicated structure of the human body and health. It took my great-grandfather his entire life to finally realize this. However, once he came to this realization, he was too aged to continue his search. Knowing that he would not be able to continue, my great-grandfather passed on his conclusions to his son, who then passed them on to his son, and my father passed the conclusions of the generations to me. My father's request was that I continue the search for this elusive "Elixir-of-Life".

I took my father's request to heart and continued the search. Armed with the information handed down to me from my father, and what I had learned on my own I began to break down the needs of people's health, and decided that my main focus should be the immune

system. To strengthen one's immune system, in my opinion, would be the closest I would be able to come to my great-grandfather's dream of an "Elixir-of-Life" and most beneficial for everyone.

My knowledge of herbalism, botany and basic potions initially, were passed down through my family. My father's knowledge was extensive and on more than one occasion he took me out to the natural environment of plants to teach me the differences, and what to look for. A few examples, would be at the age of twelve (12) my father began teaching me how to mix potions, how to isolate different properties of plant material in order to achieve a specific treatment; he also took me on more than one (1) occasion out to natural habitats to learn more about plant, their properties and how to look for what would be most beneficial from that particular plant. My father pointed out and named all of the plants able to withstand the staggering desert heat. He then took me to a Yucca plant and placed a thermometer in the plant. It was one hundred and fifteen (115°) degrees, yet the Yucca did not show any signs of stress or burn marks. The plant was not damaged in any way. My father pointed out that if this plant could withstand such an extreme environment, that there must be some benefit to be held for people. The day ended with my father pointing out all of the properties of each of the plants surrounding us. We then went home and my father had me study all of the plants that we had examined in the desert. A few months later, my father took me to an herb store in San Francisco, California, and explained the technology involved in reducing the properties of the herbs. He also explained how the conclusions that he, and generations before him had arrived at, and how with the introduction of computers, and high-tech software we would be able to expand on their conclusions and receive the maximum benefits. I began in earnest study of plants, their characteristics, their physiology and survivability. Understanding the structural function of the plants, I began experimenting on animals. As I was administering one hundred (100%) percent natural potions, I knew that the chance of a harmful side-effect was minimal.

My research entailed visiting many libraries, internet searches, as well as attending seminars, and speaking with various people in the fields of botany and herbalism. Then years of "Hit and Miss" experiments.

I also studied cells, and how they act/react. I researched the ways that protein, hormones and enzymes interact in the body, and reactions to the cells in the body. I then embarked on a study of DNA and Telomeres to understand whether it was possible to lengthen life through DNA manipulation, and telomere longevity.

I believe that my comprehensive knowledge and understanding of plant physiology, survivability and structure, along with my knowledge of the human body functions has grown through the years. Thus allowing me to incorporate the metabolic synergy of the body to be activated by plant components and plant compounds.

Initially, I was unable to run traditional scientific tests, but rather relied on the technology my father had brought from Vietnam, and conducted studies based on my understanding at the time.

With time I was able to create Golden Sunrise and have very obviously upped my testing methods.

The culmination of my life's work is a variety of Golden Sunrise products, all of which have no known side-effects to date, but my greatest achievement was the FDA approval of ***ImunStem***. My primary product to strengthen the immune system.

ImunStem, ***Aktiffvate***, and the ***KemoHerb*** dietary supplements have been under development for the past thirty (30) years. The initial development was based on assumptions different than treatment therapies used by modern medicine. They start out with a different premise, that is, a disease model. In their model, there are innumerable diseases. With the disease model, modern medicine separated the cell and its function and addresses only the results of a poor functioning cell(s) and not the cell itself. The treatment strategies deal with the symptoms and effects of the disease. This approach awarded many benefits including, not the least of which include, extending longevity and mitigating human suffering. It was a double- edged sword, however, because many of these achievements came with a price, often with side-effects, and in the end, an inability to stop the progression of chronic diseases and the multiplication of drugs to combat these diseases. They have come to a road block, largely because of the limitation of the technology that is used. They were attacking the results and symptoms created by the disease, because their technology only allowed this approach. The ***ImunStem***, ***Aktiffvate***, and ***KemoHerb*** dietary supplement development was based on a different model. In that model there is only one (1) disease. This means that if the cell becomes 'unhealthy', it becomes a ***MALFUNCTIONING*** cell, and a cascade of events occur resulting in illness. The cell and its function must both be addressed at the same time. This required a new technology. It was based on the structural function of plants and the circulatory system of plants. Basic formulations were introduced into plant structures to evaluate the responses for cell division and plant growth which ultimately lead to the final product. In vitro testing confirmed the initial plant observations to support a theory for human use. This information was then extrapolated to theorize that human tissue would demonstrate a similar characteristic of the condition, to effect repair (and)(or) reversal of the diseased state through the regeneration of cells and cellular structure for the benefit of patient's metabolism, wound, and tissue damage and debilitating diseases. This technology found the method of combining the different herbs in such a way to magnify their properties and treat the cells directly at a cellular level.

Malfunctioning cells must be the focus of attention. There is only one (1) disease in this model: a malfunctioning cell. Cells malfunction for two (2) reasons: toxins and malnutrition. By not addressing nutrition and toxicity of cells in the body, individuals will experience damage on the cellular level that result today in all of the chronic diseases, degenerative disorders, etc., which we are beleaguered with today.

There are many ways to make our bodies deficient and filled with toxins. Toxins are ubiquitous in our environment: pollution of water supplies with addition of bactericides in city water, air pollution from automotive and industrial entities, cosmetics, creams, conditioners, shampoos, hair dyes, make up, pharmaceutical medications, pesticides in food

products, etc. Poor nutrition occurs from starvation or processed foods that lack basic nutrients and contain toxins. Stress and inactivity complicate the picture as well. All the factors that contribute to the problems of a weakened body are staggering. For example, an over-taxed immune system results in body-wide 'inflammation', which perhaps is the best way to describe decreased circulation, accumulation of metabolic waste such as radicals, acid-base imbalance, localized oxygen deprivation, impaired energy production by the cells, and the list goes on. These all lead to unhealthy tissues, i.e. leaky gut problems, malabsorption, autoimmune reactions, cancer, etc. Dr. Otto Heinrich WARBURG, Nobel Prizes & Laureate, 1931, established that cancer cells derive their energy by fermentation chemical reactions and thrive in low oxygen environment (as opposed to healthy cells which require oxygen for their energy). The corollary of this is the high demand for glucose by cancer cells.

Golden Sunrise dietary supplements have established their safe and efficacy in helping to reverse, modify, or heal ***Serious or Life-threatening*** conditions. They cause release of toxins out of the cells and at the same time the herbs supply the essential nutrients which the cells have been starving for. These nutrients serve as building blocks allowing the cells to repair and rejuvenate themselves and return the cells to perform the functions they were intended to perform.

Foreign patient treatments using Golden Sunrise products. Patients have been treated in the counties of Cambodia 2-cancer-patients, China 2-cancer-patients, and Mexico 5-cancer-ptients have shown improved quality-of-life.

The **Attachment 3.1 Cancer Survival Rate Results** shows the US patients treated with only Golden Sunrise products. Other patients treated with traditional cancer treatments such as chemotherapy, radiotherapy, and surgery in addition to Golden Sunrise products have shown an improved quality-of –life.

3.0 ATTACHMENT

3.1 • **Cancer Survival Rate Results**

3.2 • **Aktiffvate Label**
- **ImunStem Label**
- **KemoHerb-1 Label**
- **KemoHerb-2 Label**
- **KemoHerb-PI Label**
- **KemoHerb-NR Label**

4.0 REFERENCES

- The Warburg effect in tumor progression: Mitochondrial oxidative metabolism as an anti-metastasis mechanism.

Golden Sunrise NUTRACEUTICAL

P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

INVESTIGATOR'S BROCHURE

ImunStem, Aktiffvate, and KemoHerbs

END

March 25, 2019

MANUFACTURE

Golden Sunrise Pharmaceutical

560 W. Putnam Avenue, Suite 2
Porterville, CA 93257

Phone No.: (559) 781-0658
Fax No.: (559) 788-2946

MIXING MANUFACTURING BATCH RECORD
CONFIDENTIAL
Golden Sunrise Pharmaceutical, Inc.
560 W. Putnam Avenue, Suite 2 * Porterville, CA 93257

Batch No.: GS-0000001 **Item No.: IS-01** **Description: ImunStem**	**Order Quantity** (b) (4) **Page: 1 of 6**

Item (#)	Description	Claim per Serving (ml)	Overage (%)	Quantity Requested	Unit of Measure	Quantity Issued	Batch (#)	Complete by/Date	Verify by/Date
(b) (4)					Fluid ounces (fl.oz.)	(b) (4)	150001	M 03-17-15	03-17-15
					Fluid ounces (fl.oz.)		150002	M 03-17-15	03-17-15
					Fluid ounces (fl.oz.)		150003	M 03-17-15	03-17-15

Each component must be within (b) (4)

Total volume in ounces: (b) (4)

Master Manufacturing Record Approvals:

DOCUMENT NAME: Manufacturing Batch Record (MBR) - Item Number (#) and Bulk Liquid			
REVISION NUMBER	REVISON DATE	APPROVALS	
		Production	Quality
A		[signature]	[signature]
		03-17-2015	03-17-2015

MIXING MANUFACTURING BATCH RECORD
CONFIDENTIAL
Golden Sunrise Pharmaceutical, Inc.
560 W. Putnam Avenue, Suite 2 * Porterville, CA 93257

Batch No.: GS-0000001 **Item No.: IS-01** **Description: ImunStem**	**Order Quantity:** (b) (4) **Page: 2 of 6**

REPRESENTATIVE LABEL SAMPLE

ImunStem®
For Oral Solution

WARNING
Keep Out of Reach of Children
do not use if safety seal is damaged or missing

Golden Sunrise Pharmaceutical, Inc.

Net Content: (1 fl.oz.)

SUPPLEMENT FACTS
Serving Size: (0.50 – 1.00ml) (491.50ml)
Serving Per Container: 25 – 50 serving

Amount Per Serving		**%DV**
Olive Leaf extract	260mg	**
Yarrow extract	52mg	**
Rosemary extract	63mg	**

** Daily Value (DV) not established.

Other ingredients: d-Limonene, solvents, organic compounds, Cassia oil and Yucca extract.

Expiration date: April 2018

Golden Sunrise Pharmaceutical, Inc.

P.O. Box 510 * Porterville, CA 93258
Fax No.: (559) 788 - 2946
Phone No.: (559) 781 - 0658

CERTIFICATE OF ANALYSIS

Name: Golden Sunrise Pharmaceutical, Inc.

Product Name: IMUNSTEM

Item Number: IS-01

Lot Number: A1500001

Ship Date: March 25, 2015

Date of Manufacture: March 17, 2015

ANALYTICAL RESULTS

Determination	Units	Specifications	Result	Test Method
pH		(b) (4)	6.70	N/A
Type	Liquid		Confirms	N/A
Color			Black	N/A
Brix	Percent (%)		37	N/A
Odor	Characteristic		Confirms	Smell
Taste	Characteristic		Confirms	Oral Taste

REMARKS:

Golden Sunrise Pharmaceutical, Inc.

P.O. Box 510 * Porterville, CA 93258
Fax No.: (559) 788 - 2946
Phone No.: (559) 781 - 0658

Product Name: ImunStem
Item No.: IS-01
Lot No.: A1500001
Expiration Date: April, 2018

Imunstem®
Dietary Supplement

WARNING
Keep Out of Reach of Children
Do not use if safety seal is damaged or missing

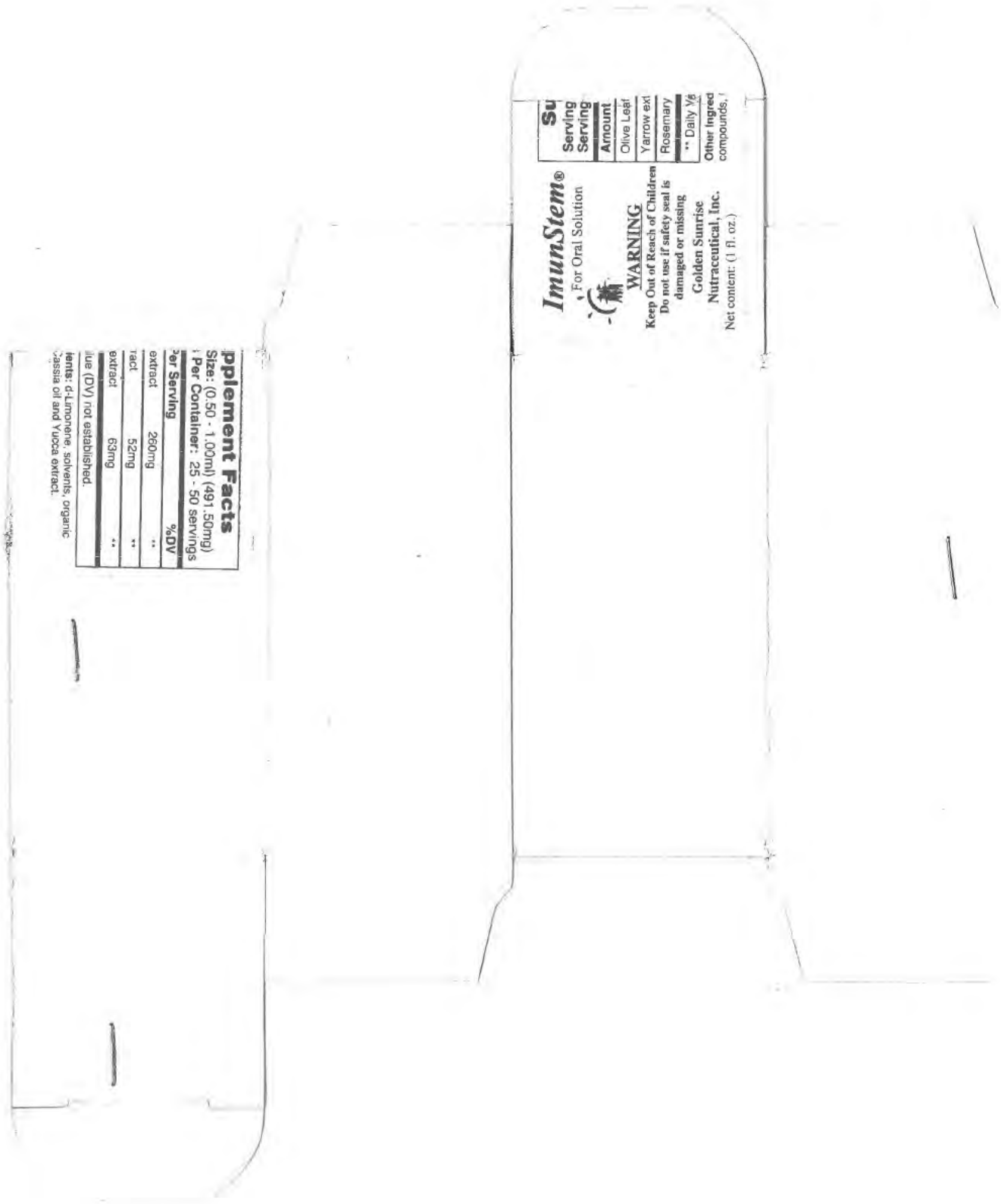
Golden Sunrise Nutraceutical, Inc.
Net content: (1 fl. oz.)

Supplement Facts
Serving Size: (0.50 - 1.00ml) (491.50mg)
Servings Per Container: 20 servings

Amount Per Serving		%DV
Olive Leaf extract	260mg	**
Yarrow extract	52mg	**
Rosemary extract	63mg	**

** Daily Value (DV) not established.

Other Ingredients: d-Limonene, solvents, organic compounds, Cassia oil and Yucca extract.



ImunStem®
For Oral Solution

WARNING
Keep Out of Reach of Children
Do not use if safety seal is damaged or missing

Golden Sunrise Nutraceutical, Inc.

Net content: (1 fl. oz.)

Su
Serving
Serving

Amount
Olive Leaf
Yarrow ext
Rosemary
** Daily Va

Other Ingred
compounds,

pplement Facts
Size: (0.50 - 1.00ml) (491.50mg)
Per Container: 25 - 50 servings

er Serving		%DV
extract	260mg	**
ract	52mg	**
extract	63mg	**
lue (DV) not established.		

ients: d-Limonene, solvents, organic assia oil and Yucca extract.

MANUFACTURE

WEPACKITALL

2745 Huntington Drive
Duarte, CA 91010

Phone No.: (626) 301-9214
Fax No.: (626) 301-9216

NSF International
789 Dixboro Road, Ann Arbor, Michigan 48105
(800) 673-6275

GMP Registered
www.nsf.org

WePackItAll

2745 Huntington Drive
Duarte, CA 91010

has been assessed by NSF International and found to be in compliance with:

GMP Requirements in NSF/ANSI Standard 173, Section 8

DIETARY SUPPLEMENTS

September 13, 2012
Certificate Number: C0094422 - 03
Initial Certification: April 13, 2012

Edward Wyszumiala, General Manager
Dietary Supplements

KG

LIQUID IMUNSTEM -5J2

LOT: A1500001 *SURPLUS*
HEAT: S 04/01/2018
SERIAL: 1BT[illegible] (b) (4) KG F0018563

W/O:
S/O:
P/O:

3PLS@ (b) (4) KG

2015-04-16

CUST:
VEND:

04/16/15 9:08 AM BIN to BIN TRANSFER

ALVARON

INITIALS

WePackItAll

From: 3/21/2015 To: 3/21/2015

Customer Receiving Log

Part	Description	Quantity UM	Lot	Heat/Exp Dt	Serial	Recv Dt	Typ	UserID
GOLDEN SUNRISE PHARMACEUTICAL (2889)								
2889-001	LIQUID IMUNSTEM	(b) (4)	2889-001	H N/A	(b) (4)	03/21/15	A10	RANDYV
2889-400	BOTTLE 1OZ AMBER GLASS		N/A	H N/A		03/21/15	A10	RANDYV
2889-401	CAP 18MM BLACK CAP		N/A	H N/A		03/21/15	A10	RANDYV

*** End of Report ***

03/21/15 1:55 pm
INV016GI-002576

WEPACKITALL
Physical Inventory Onhand Changes Audit

Tran Code	Part Number	LC	Date	Bin	Onhand - From	Onhand - To	Cost	Value Change
P16	2889-001 Lot: 2889-001		3/21/2015 Heat: H N/A	W2CAGE	(b) (4)		.0000	.0000
P16	2889-001 Lot: A1500001		3/21/2015 Heat: MISSING	W2CAGE			.0000	.0000

Grand Total:

GOLDEN SUNRISE

2889-001 LIQUID IMUNSTEM LOT# A1500001

(b) (4)

2889-400 1oz AMBER GLASS BOTTLES

(b) (4)

2889-401 18MM BLACK CAP

(b) (4)

WePackItAll GOLDEN SUNRISE PHARMACEUTICAL (2889) **Customer Inventory - Components**

Cust Part#	Part#	Description	Bin	Qty On-Hand UM	Serial	Lot	Heat/Exp Dt
	2889-001	LIQUID IMUNSTEM	W2-5J2	(b) (4)	1BT=16.32 KG F0018563	A1500001	S 04/01/2018
		Total for part 2889-001:					
	2889-401	CAP 18MM BLACK CAP	W2-4I2		1BG=228 EA N0018595	N/A	S N/A
		Total for part 2889-401:					
	2889-402	LABEL IMUNSTEM 1FL OZ	W213L1		1RL=1,250 EA N0018663	N/A	S N/A
		Total for part 2889-402:					

*** End of Report ***

3 Items

04/20/15 11:52:55AM

Expired or Quarantined Parts are shown in Red.

\\gsserver\globapps\Global\busint\WPIA_Customer_Inventory_Report_Components only.rpt

Page 1 of 1

Exhibit JAG-21
Golden Sunrise Pharmaceutical Inc.
FEI 3012327979
2/19/19-3/22/19 JAG 14 of 34

INVENTORY R)ORT

FG BY CUSTOMER

4/20/2015)):50:27AM

GOLDEN SUNRISE PHARMACEUTICAL

2889

No	Part No	Description	Qty	Bin	Lot No	Exp Date	Serial	Breakdown
2889	T9463	IMUNSTEM 1FL OZ BOTTLE	(b) (4)	W2-7F1	IS00001	04/01/2016	#1 WO 031426-001	(b) (4)

*******Part has Sales Orders on HOLD*******

(b) (4)

Record Count : 1 **Total for Part : 1,776.00** **BT**

(b) (4)

Important: For customers where no warehousing agreement is in place, shipment arrangements should be made immediately upon completion of production, or full truckload quantities, whichever comes first. In the event of a delayed shipment of finished goods, in excess of 10 days, standard warehousing fees of $45.00 per pallet/per month (billed in full-month increments) will be assessed.

Divide by KL. (b) (4)

Golden Sunrise

Packing Slip

2889-001
3/20/15
12:30

(b) (4)
2 lbs

Imunstem
Lot # A1500001
EXP: 4/2018

(b) (4) Bottles (b) (4)

Black Caps
Qty: (b) (4)

1oz Amber Jars
(b) (4)

3/20/15 2:30

Black Caps

(b) (4) @ (b) (4) dozen - (b) (4)
@ dozen -

1oz Amber Jars
4 boxes (b) (4)

1oz Amber Jars
(b) (4)

X [redacted] 3/20/15

[redacted]

X

Golden Sunrise
Packing Slip

Imunstem
Lot # A1500001
EXP: 4/2018
(b) (4) Bottles

BlackCaps
Qty (b) (4)

1oz Amber Jars
(b) (4)

X [redacted] 3/20/15
[redacted]

X

Golden Sunrise
Packing Slip

3/20/15 12:30

Imunstem
Lot # A150000 1
EXP: 4/2018
(b) (4) Bottles

Black Caps
Qty: (b) (4)

1oz Amber Jars
(b) (4)

3/20/15 2:30

Black Caps
(b) (4) @ (b) (4) dozen
@ dozen

1oz Amber Jars
(b) (4)

X [redacted] 3/20/15
[redacted]

X

Golden Sunrise Pharmaceutical, Inc.

P.O. Box 510 * Porterville, CA 93258
Fax No.: (559) 788 - 2946
Phone No.: (559) 781 - 0658

ImunStem®
For Oral Solution

WARNING
Keep Out of Reach of Children
do not use if safety seal is damaged or missing

Golden Sunrise Pharmaceutical, Inc.

Net Content: (1 fl.oz.)

SUPPLEMENT FACTS
Serving Size: (0.50 – 1.00ml) (491.50ml)
Serving Per Container: 25 – 50 serving

Amount Per Serving		%DV
Olive Leaf extract	260mg	**
Yarrow extract	52mg	**
Rosemary extract	63mg	**

** Daily Value (DV) not established.

Other ingredients: d-Limonene, solvents, organic compounds, Cassia oil and Yucca extract.

Expiration date: April 2018

ImunStem®

For Oral Solution

WARNING

Keep Out of Reach of Children
Do not use if safety seal is damaged or missing

Golden Sunrise Pharmaceutical, Inc.

Net content: (1 fl. oz.)

Supplement Facts

Serving Size: (0.50 - 1.00ml) (491.50mg)
Servings Per Container: 25 - 50 servings

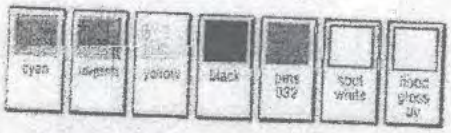
Amount Per Serving		%DV
Olive Leaf extract	260mg	**
Yarrow extract	52mg	**
Rosemary extract	63mg	**

** Daily Value (DV) not established.

Other Ingredients: d-Limonene, solvents, organic compounds, Cassia oil and Yucca extract.

Expiration date: April, 2018

Proof Size: 100%



Layout Size: " web x " repeat

Material: ss

Unwind Direction: #4

CHECK BOX AND SIGN BEFORE RETURNING PROOF

- [ ] PROOF IS OK TO PRINT
- [ ] PROOF IS OK WITH CORRECTIONS — SIGN:
- [ ] PRESENT ANOTHER PROOF — DATE:

PLEASE READ CAREFULLY

This proof is presented for your approval of **typographical accuracy, layout and style.** Although every effort has been made to provide correct copy, we cannot assume responsibility in case of errors found in the finished product that were not indicated on this proof.

Golden Sunrise Pharmaceutical Incorporation

MATERIAL SAFETY DATA SHEET

1.0 PRODUCT IDENTIFICATION

Trade Name: ImunStem®
Product Use: Dietary Supplement

Manufacturer: Golden Sunrise Pharmaceutical Incorporation
P.O. Box 510
Porterville, CA 93258

Emergency Phone: 559-788-2940
Business Phone: 559-361-0097

Name of Preparer: Golden Sunrise
Date Prepared: October 2008

2.0 INGREDIENTS

Chemical Names	CAS Numbers	Percent (%)	Exposure Limits TLV/PEL
(b) (4)			

Ingredients not precisely identified as proprietary or none hazardous.
Values are not product specifications.

3.0 PHYSICAL PROPERTIES

pH:	4.00 – 5.00
Viscosity:	6.30
Corrosion rate:	17.20
Melting point or range, F:	N/A
Specific gravity:	0.9812
Boiling point or range, F:	207° degree F
Solubility:	100% in solution, in water.
Vapor pressure (mmHg at 20 degree C)	0.25 PSI
Evaporation rate (butyl acetate = 1)	N/A
Appearance and odor	A dark brown liquid with citrus and cinnamon type fragrance.

4.0 FIRE AND EXPLOSION

Flammable limits in air, volume %:	Non-flammable
Fire extinguishing materials:	None
Special firefighting procedures:	None
Flash point:	None

Golden Sunrise Pharmaceutical, Inc.

P.O. Box 510 * Porterville, CA 93258
Fax No.: (559) 788 - 2946
Phone No.: (559) 781 - 0658

CERTIFICATE OF ANALYSIS

Name: Golden Sunrise Pharmaceutical, Inc.

Product Name: IMUNSTEM

Item Number: IS-01

Lot Number: A1500001

Ship Date: March 25, 2015

Date of Manufacture: March 17, 2015

ANALYTICAL RESULTS

Determination	Units	Specifications	Result	Test Method
pH		(b) (4)	6.70	N/A
Type	Liquid		Confirms	N/A
Color			Black	N/A
Brix	Percent (%)		37	N/A
Odor	Characteristic		Confirms	Smell
Taste	Characteristic		Confirms	Oral Taste

REMARKS:

WePackItAll
2745 E. HUNTINGTON DR
DUARTE CA 91010
PH 626-301-9214
FAX 626-301-9216
Contract Packaging Associates
California Certified Organic Packager - Reg #23998

PACKING LIST
056692

Special Instructions
☒ Partial Ship ☐ Complete Ship
APPROVED FOR SHIPPING
By: _____
Date: _____

SOLD TO:
GOLDEN SUNRISE PHARMACEUTICAL
PO BOX 510
PORTERVILLE CA 93258

Cust No
2889

SHIP TO:
GOLDEN SUNRISE PHARMACEUTICAL
PO BOX 510
PORTERVILLE CA 93258

Sales Order	Shipment No	Order Date	Promised	Sales Rep	Customer P.O. Num
0031426	0002	03/10/15	04/03/15	MONICA BARRAGAN	A030915
BOL #		**Ship Date**	**Cartons**	**Weight (LB)**	**Ship Via:** PENDING
000015403		04/20/15	77	225.00	

Item	QUANTITY Order	B/O	Ship	Unit	Part Number	Description
001	(b) (4)	(b) (4)	(b) (4)	BT	T9463 Qty (b) (4) Lot IS00001 Serial No.	IMUNSTEM 1FL OZ BOTTLE 74CS@24EA Bin W2-7F1 Heat 04/01/2016 # 1 WO 031426-001
004				KG	2889-001 Qty (b) (4) Lot A1500001 Serial No.	LIQUID IMUNSTEM Bin W2-5J2 Heat S 04/01/2018 1BT=16.32 KG F0018563
005				EA	2889-401 Qty (b) (4) Lot N/A Serial No.	CAP 18MM BLACK CAP Bin W2-4I2 Heat S N/A 1BG=228 EA N0018595
006				EA	2889-402 Qty (b) (4) Lot N/A Serial No.	LABEL IMUNSTEM 1FL OZ Bin W213L1 Heat S N/A 1RL=1,250 EA N0018663

CA Organic Registration #23998

ENTERED BY: TERMINAL 262

Date: 4/20/2015

BILL OF LADING

Page 1

SHIP FROM

Name: WEPACKITALL
Address: 5001 - UNIT A COMMERCE DRIVE
Frt Trm:
Phn:
Fax:
City/St/Zip: BALDWIN PARK CA 91706
California Certified Organic Packager - Reg #23998

Bill of Lading Number: 000015403

SHIP TO

Name: GOLDEN SUNRISE PHARMACEUTICAL
Address: PO BOX 510
Location#:
City/State/Zip: PORTERVILLE CA 93258

CARRIER NAME:
Trailer Number:
Seal Number(s):
SCAC:
Pro Number:

THIRD PARTY FREIGHT CHARGES BILL TO

Name:
Address:
City/State/Zip:

Freight Charge Terms: *(Freight charges are prepaid unless marked otherwise)*
Prepaid____ Collect____ 3rd Party____

SPECIAL INSTRUCTIONS:

☐ (check box) Supplemental Form Required When Box Checked

CUSTOMER ORDER INFORMATION

CUSTOMER ORDER NUMBER	CUSTOMER PO #	ADDITIONAL SHIPPER INFO
056692 - 0031426 - 0002	A030915	

CARRIER INFORMATION

HANDLING UNIT QTY	HANDLING UNIT TYPE	PACKAGE QTY	PACKAGE TYPE	WEIGHT	H.M. (X)	COMMODITY DESCRIPTION (Commodities requiring special or additional care or attention in handling or stowing must be so marked and packaged as to ensure safe transportation with ordinary care. See Section 2(e) of NMFC Item 360)	LTL ONLY NMFC#	LTL ONLY CLASS
1	PALLET	(b) (4)	BOX	(b) (4)		FOOD SUPPLEMENT		70
			EA			SURPLUS		70
1						GRAND TOTAL		

Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property as follows:
"The agreed or declared value of the property is specifically stated by the shipper to be not exceeding _____ per _____."

COD Amount: $_____
Fee Terms: Collect: ☐ Prepaid: ☐
Customer Check Acceptable: ☐

NOTE Liability Limitation for loss or damage in this shipment may be applicable. See 49 U.S.C. #14706(c)(1)(A) and (B).

RECEIVED: subject to individually determined rates or contracts that have been agreed upon in writing between the carrier and shipper, if applicable, otherwise to the rates, classifications and rules that have been established by the carrier and are available to the shipper, on request, and to all applicable state and federal regulations.

The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

_____ Shipper Signature

SHIPPER SIGNATURE AND / DATE

This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to applicable regulations of the U.S. DOT.

Trailer Loaded:
☐ By Shipper
☐ By Driver

Freight Counted:
☐ By Shipper
☐ By Driver/pallets said to contain
☐ By Driver/Pieces

CARRIER SIGNATURE / PICKUP DATE

Carrier acknowledges receipt of packages and required placards. Carrier certifies emergency response information was made available and/or carrier has the U.S. DOT emergency response guidebook or equivalent documentation in the vehicle.

\\gsserver\globapps\Global\busint\WPIA_OE_WAYBILL.RPT

RE: Labels for Golden Sunrise Pharmaceuti cal Monday, March 23, 2015 3:49 PM

From: "Monica Barragan" <monicab@wepackitall.com>

To: "Joseph Puleo" <qualitylabel@cox.net>

Cc: "Huu Tieu" <htieu@goldensunrisepharmaceutical.com>

1 Files 284KB Download All

PDF 284KB

CCF032 32015_0 0000.pdf

Save

Artwork prrof needs to be layout as the attached sample.

Please include the material

Thank you,

Monica Barragan
WEPACKITALL
2745 Huntington Drive
Duarte, CA 91010
Tel 626-301-9214, Ext 120
Fax 626-301-9216

Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.

From: Joseph Puleo [mailto:qualitylabel@cox.net]
Sent: Monday, March 23, 2015 1:58 PM
To: Monica Barragan
Cc: qualitylabel@cox.net; Huu Tieu
Subject: Re: Labels for Golden Sunrise Pharmaceutical

Monica Barragan,

Attached is a proof of the label for Golden Sunrise Pharmaceutical, Inc.
Dimensions: 3.75" x 1.75"
3" Core
Under 11" O.D.
Roll Direction #4
1/8" Gap Between

Thank you.
Joseph Puleo
Quality Label
888-284-5969

On Mar 23, 2015, at 3:39 PM, Monica Barragan wrote:

> Please add the dimensions of the label on the Layout proof
>
>
> Thank you,
>
> Monica Barragan
> WEPACKITALL
> 2745 Huntington Drive
> Duarte, CA 91010
> Tel 626-301-9214, Ext 120
> Fax 626-301-9216
>
> Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.
>
>
> -----Original Message-----
> From: Joseph Puleo [https://us-mg6.mail.yahoo.com/neo/b/compose?to=qualitylabel@cox.net]
> Sent: Monday, March 23, 2015 12:02 PM
> To: Monica Barragan
> Cc: https://us-mg6.mail.yahoo.com/neo/b/compose?to=qualitylabel@cox.net; Huu Tieu
> Subject: Labels for Golden Sunrise Pharmaceutical
>
> Monica Barragan,
>
> Attached is a proof of the label for Golden Sunrise Pharmaceutical, Inc.
> 3" Core
> Under 11" O.D.
> Roll Direction #4
> 1/8" Gap Between
>
> Thank you.
> Joseph Puleo
> Quality Label
> 888-284-5969

Golden Sunrise Pharmaceutical, Inc.

P.O. Box 510
Porterville, CA 93258
(559) 361-0097

Purchase Order

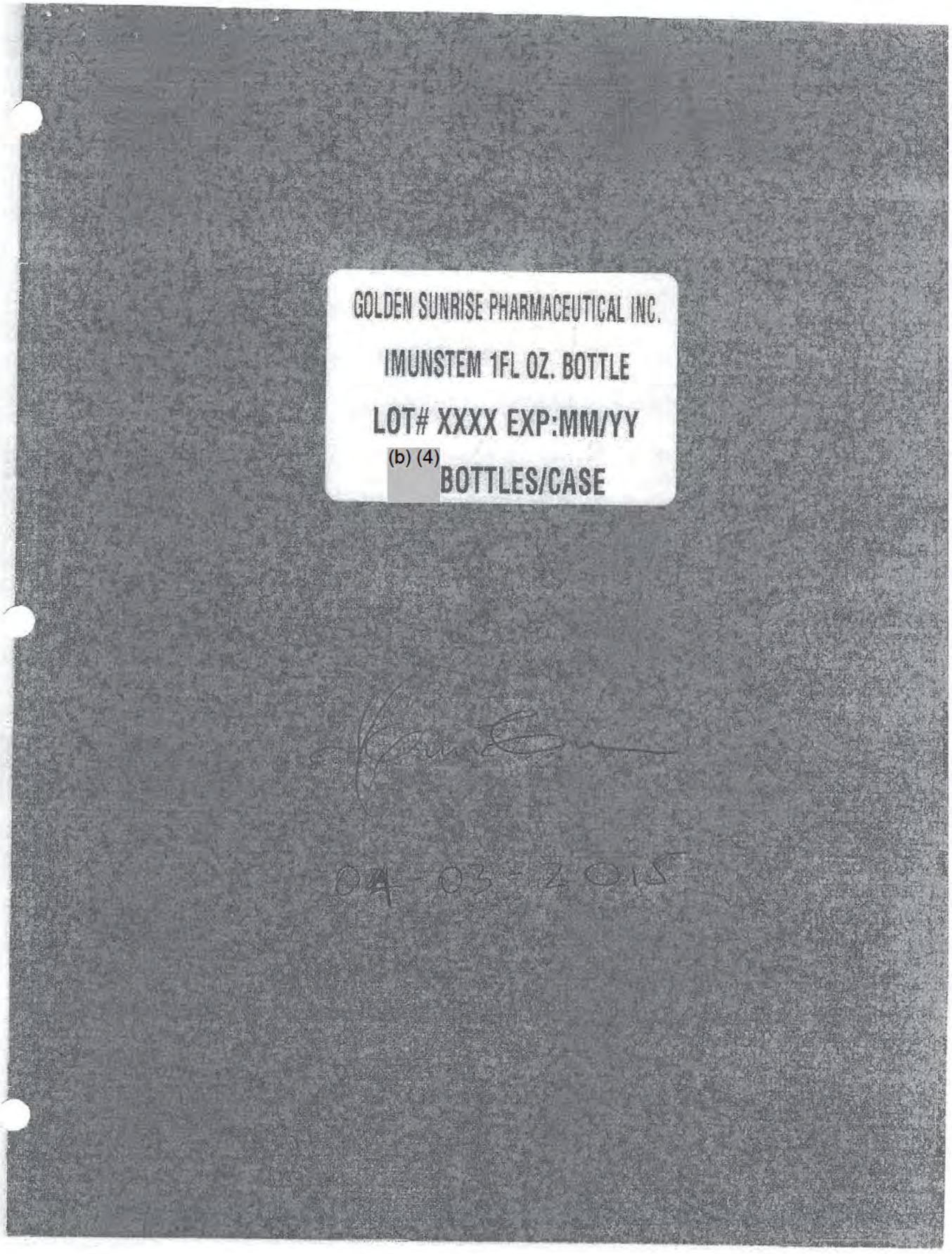
Date	P.O. No.
3/9/2015	A030915

Vendor
WePackItAll 2745 Huntington Drive Duarte, CA 91010

Ship To
WePackItAll 2745 Huntington Drive Duarte, CA 91010

Item	Description	Qty	Rate	Amount
ImunStem	ImunStem 1 fl.oz. bottle	(b) (4)	1.49	(b) (4)

Total (b) (4)


GOLDEN SUNRISE PHARMACEUTICAL INC.
IMUNSTEM 1FL OZ. BOTTLE
LOT# XXXX EXP:MM/YY
(b) (4) BOTTLES/CASE
04-03-2015

WePackItAll

2745 Huntington Drive
Duarte, CA 91010
626-301-9214

Material Destruction Authorization

Customer ID#:	**2889 – Golden Sunrise**	**Date:**	**06/21/16**	**Reference #:**	**244**
	Raw Material		X	**Packaging Components**	
	Bulk		X	**Labels**	
	Finished Goods, Other:			**Records**	
Rejected From:		**Quarantine**	X	**Stock**	

Customer Part #	Quantity	Product Description	LOT NO./ Exp.	Reason For Destruction
2889-402	(b) (4) ea	Label Imunstem 1fl oz	N/A	OLD INVENTORY

Reason for Request:
Old Inventory

Requested By:
Huu S. Tieu from Golden Sunrise

Q.A/Q.C. Evaluation n/a BY n/a

Additional Remarks: n/a BY n/a

APPROVALS

Brenda Leos 6/21/16
QA/QC Approval Date

Monica Barrigan 6-21-16
Customer/ Account Representative Date

Carried Out By: Date: 6/22/16 Print Name: Brenda Leos

Signature: Brenda Leos

WP940A Rev 0

RE: Surplus Bulk

Monica Barragan <monicab@wepackitall.com>

Wed 6/22/2016 2:11 PM

To:Huu Tieu <htieu@goldensunrisepharmaceutical.com>;

1 attachment (280 KB)

MD #244.pdf

Hi Huu,

Attached is the destruction paperwork for your records.

Thank you,

Monica Barragan
WEPACKITALL
2745 Huntington Drive
Duarte, CA 91010
Tel 626-301-9214, Ext 120.
Fax 626-301-9216

Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.

From: Huu Tieu [mailto:htieu@goldensunrisepharmaceutical.com]
Sent: Friday, June 17, 2016 2:57 PM
To: Monica Barragan <monicab@wepackitall.com>
Subject: Re: Surplus Bulk

Dear Ms. Barragan,

Yes, Thank you.

Huu S. Tieu, President
Golden Sunrise Pharmaceutical, Inc.

From: Monica Barragan <monicab@wepackitall.com>
Sent: Friday, June 17, 2016 12:36:46 PM

To: Huu Tieu
Cc: Roberto Hernandez
Subject: FW: Surplus Bulk

Hi Huu,

Per our telephone conversation yesterday, please confirm that we can dispose of the labels that we currently have on hand. Please advise ASAP.

Thank you,

Monica Barragan
WEPACKITALL
2745 Huntington Drive
Duarte, CA 91010
Tel 626-301-9214, Ext 120
Fax 626-301-9216

Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.

From: Monica Barragan
Sent: Tuesday, June 07, 2016 3:05 PM
To: 'Huu Tieu' <htieu@goldensunrisepharmaceutical.com>
Subject: FW: Surplus Bulk
Importance: High

Hi Huu,

Do you have an update on the below disposition?

Thank you,

Monica Barragan
WEPACKITALL
2745 Huntington Drive
Duarte, CA 91010
Tel 626-301-9214, Ext 120
Fax 626-301-9216

Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.

From: Monica Barragan
Sent: Friday, June 03, 2016 4:06 PM
To: 'Huu Tieu' <htieu@goldensunrisepharmaceutical.com>; Roberto Hernandez <robertoh@wepackitall.com>
Subject: FW: Surplus Bulk
Importance: High

Hi Huu,

Happy Friday. Do you have an update on the below disposition?

Please note that if do not hear back from you by June 17, 2016 we will start invoicing your company for a storage fees.

Thank you.

Monica Barragan
WEPACKITALL
2745 Huntington Drive
Duarte, CA 91010
Tel 626-301-9214, Ext 120
Fax 626-301-9216

Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.

From: Monica Barragan
Sent: Thursday, May 19, 2016 8:06 AM
To: 'Huu Tieu' <htieu@goldensunrisepharmaceutical.com>
Cc: Roberto Hernandez <robertoh@wepackitall.com>
Subject: Surplus Bulk

Hi Huu,

We have recently reviewed our product inventory in our warehouse and discovered the attached items belonging to you from a previous packaging job. Please see attachment.

Please advise in writing as to their disposition. We will be glad to send them to you at your expense or dispose of them.

Thank you,

Monica Barragan
WEPACKITALL
2745 Huntington Drive
Duarte, CA 91010
Tel 626-301-9214, Ext 120
Fax 626-301-9216

Note: All trucks must call WEPACKITALL in advance and schedule a time for a pick-up or delivery. Please ensure all deliveries contain proper documentation (I.E. packing slips, C of A's, lot number, exp date, MSDS, etc..) upon delivery. We appreciate your cooperation in meeting this requirement to create a more effective warehouse structure. Please call to schedule an appointment at 626-962-2772.

Attachment G

Golden Sunrise NUTRACEUTICAL

TITLE

PRIMARY Plan of Care

PRODUCTS

ImunStem and Aktiffvate

COMPANY

Golden Sunrise Nutraceutical, Inc.
219 N. "E" Street
PORTERVILLE, CA 93257 * U.S.A.
Phone No.:1.559.781.0658
Fax No.: 1.559.615.1268

Golden Sunrise NUTRACEUTICAL

TABLE OF CONTENTS

Golden Sunrise NUTRACEUTICAL

1.0 INTRODUCTION

This guidance is designed as the first use Primary Plan of Care for all conditions or diseases and is used to stabilize the patient. It has been found that under so many varying and unknown conditions that physicians and medical professional's encounter a varying degree of problems associated to the physical health of their patients and that a Primary Plan of Care is needed to address each circumstance.

2.0 TREATMENT

2.1 Administration of ImunStem and Aktiffvate

Upon the first visit it is suggested that once a medical evaluation of the patient is completed and that the medical staff deems appropriate, then ¾ of a dropper of ***ImunStem*** is given to the patient. The medical staff should monitor the patient for at least thirty (30) minutes to notice any effects that might need other medical attention as ***ImunStem*** can open and improve blood flow throughout the body and the patient might experience feeling of warmth and a discharge of mucus that may need to be addressed. After thirty (30) minutes if the patient is stable, the ¾ of a dropper of ***Aktiffvate*** should be administered with similar monitoring. Please refer **Attachment 3.1 ImunStem Dietary Supplement Label** and **Attachment 3.2 Aktiffvate Dietary Supplement Label**.

2.2 Ongoing Treatment

The patient should receive ½ to ¾ of a dropper of ***ImunStem*** and ***Aktiffvate*** between three to four (3-4) times daily for the first two (2) weeks then another evaluation should be performed to ascertain the effect and if the dose can be reduced to two to three (2-3) times daily. Once this treatment therapy has completed thirty (30) days then a blood test should be conducted to evaluate effectiveness. If the patient's body appears to be stable then to see if other Golden Sunrise Nutraceutical products supplementation should be added to specific conditions or diseases of the patient. All future treatments should take into account any physicians evaluations, blood reports or other information pertinent to the treatment of the patient.

3.0 ATTACHMENT

3.1 ImunStem Dietary Supplement Label
3.2 Aktiffvate Dietary Supplement Label

Golden Sunrise NUTRACEUTICAL

3.0 ATTACHMENT

3.1 ImunStem Dietary Supplement Label, and
3.2 Aktiffvate Dietary Supplement Label

ImunStem®

Dietary Supplement

WARNING

Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (0.50ml) (491.50mg)		
Serving Per Container: 50 serving		
Amount Per Serving		**%DV**
Olive leaf extract	260mg	**
Yarrow flower extract	52mg	**
Rosemary extract	63mg	**
** Daily Value (DV) not established.		

Other ingredients: solvent, organic compounds, monoterpene, fatty acid, cassia oil, and yucca.

"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"

Adverse Actions

- In rare circumstances an adverse reaction in the month such as "mild blisters" have occurred.
- A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a benefit response.
- Vomiting.
- Yarrow flowers can cause severe allergic skin rashes.

Administration: Shake bottle well before using and use dropper to place zero point fifty (0.50ml) of *ImunStem* under tongue. Leave under tongue for approx. forty (40) seconds and then drink water.

Dosage: Take ½ – ¾ quarter of a dropper, 1-4 times a day, between one (1) and three (3) hours.

ImunStem dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***ImunStem***, please consult your doctor or call the product hot line in U.S.A. at 1(559) 361-0097 or 1(559) 781-0658. Keep out of reach of children. To be kept in a dry and cool place.

- These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 510, PORTERVILLE, CA 93258 * U.S.A.
ImunStem is a Registered Trademark of Golden Sunrise Pharmaceutical, Inc.

Aktiffvate®

Dietary Supplement

WARNING

Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS **Serving Size:** (0.50ml) (491.50mg) **Serving Per Container:** 50 serving		
Amount Per Serving		**%DV**
Turmeric extract	175mg	**
Cayenne extract	40mg	**
Eucalyptus extract	20mg	**
** Daily Value (DV) not established.		

Other ingredients: solvent, organic compounds, fatty acid, Wintergreen, Yucca, and Olive leaf.

"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

Adverse Actions

- In rare circumstances an adverse reaction in the month such as "mild blisters" have occurred.
- A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a benefit response.
- Vomiting.

Administration: Shake bottle well before using and use dropper to place zero point fifty (0.50ml) of ***Aktiffvate*** under tongue. Leave under tongue for approx. forty (40) seconds and then drink water.

Dosage: Take ½ – ¾ quarter of a dropper, 1-4 times a day, between one (1) and three (3) hours.

Aktiffvate dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***Aktiffvate***, please consult your doctor or call the product hot line in U.S.A. at 1(559) 361-0097 or 1(559) 781-0658. Keep out of reach of children. To be kept in a dry and cool place.

- These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 510, PORTERVILLE, CA 93258 * U.S.A.
Aktiffvate is a Registered Trademark of Golden Sunrise Pharmaceutical, Inc.

Golden Sunrise NUTRACEUTICAL

PRIMARY Plan of Care

January, 2018

THE END

Golden Sunrise NUTRACEUTICAL

TITLE

CANCER Plan of Care

PRODUCTS

KemoHerb

COMPANY

Golden Sunrise Nutraceutical, Inc.
219 N. "E" Street
PORTERVILLE, CA 93257 * U.S.A.
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

Golden Sunrise NUTRACEUTICAL

TABLE OF CONTENTS

1.0 INTRODUCTION

An overview of the ***KemoHerb*** treatment is as follows. First ***ImunStem*** and ***Aktiffvate*** are provided, approximately two (2) weeks before ***KemoHerb*** is administered. ***ImunStem*** and ***Aktiffvate*** are taken simultaneously for the two (2) weeks. Patients will receive ½ to ¾ of a dropper three to four (3-4) times a day during this time period. Following these two (2) weeks a blood test must be taken to ascertain whether or not the patient is ready to receive the ***KemoHerb*** treatment. If patient shows appropriate improvement in general health, the dosage will continue at ½ of a dropper. Additional testing occurs thirty (30) days following initiation of ***ImunStem*** and ***Aktiffvate***. These products will improve the function of the Immune system, as well as overall health. This step is very important, as it will maximize the effect of ***KemoHerb***. If patient's condition is appropriate improve and stable, other Golden Sunrise Nutraceutical products may be supplemented for patient's specific condition. Please refer **Attachment 3.3 ImunStem Dietary Supplement Label** and **Attachment 3.4 Aktiffvate Dietary Supplement Label**.

2.0 TREATMENT

FIRST AND FOREMOST, ***KEMOHERB*** MUST BE ADMINISTERED UNDER THE SUPERVISION OF A PHYSICIAN'S CARE. Once a medical evaluation of the patient has been completed, and reviewed; those patients whose medical history, and current medical condition is appropriate for treatment with ***KemoHerb*** will receive the product as follows:

2.1 Administration of KemoHerb

Drink one (1 fl.oz.) fluid ounce of ***KemoHerb-1***. Medical staff should monitor the patient for forty (40) minutes to one (1) hour following ingestion of ***KemoHerb-1***. Next ***KemoHerb-2*** is administered in the same dosage, and again medical staff should monitor the patient for thirty (30) minutes following of ***KemoHerb-2***. Please refer **Attachment 3.1 KemoHerb-1 Dietary Supplement Label** and **Attachment 3.2 KemoHerb-2 Dietary Supplement Label**.

The ***KemoHerb*** has no toxic "side-effects". It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, and mucus discharges. Other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

WARNING: ADMINISTRATION OF ***KEMOHERB*** SHOULD ALWAYS BE UNDER THE SUPERVISION OF A PHYSICIAN. REFERRAL OF ***GOLDEN SUNRISE NUTRACEUTICAL*** PRODUCTS IS BASED ON MEDICAL EVALUATION PROVIDED OF THE PATIENT, AND LABORATORY WORK RESULTS.

3.0 ATTACHMENT

- **3.1 KemoHerb-1 Dietary Supplement Label**
- **3.2 KemoHerb-2 Dietary Supplement Label**
- **3.3 ImunStem Dietary Supplement Label**
- **3.4 Aktiffvate Dietary Supplement Label**

Golden Sunrise NUTRACEUTICAL

CANCER Plan of Care

January, 2018

END

Golden Sunrise NUTRACEUTICAL

3.0 ATTACHMENT

3.1 KemoHerb-1 Dietary Supplement Label,
3.2 KemoHerb-2 Dietary Supplement Label,
3.3 ImunStem Dietary Supplement Label, and
3.4 Aktiffvate Dietary Supplement Label

KemoHerb™-1

Dietary Supplement

WARNING

Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Bilberry leaf	40mg	**
Graviola extract	120mg	**
Goldenseal extract	80mg	**
** Daily Value (DV) not established.		

Other ingredients: solvent, organic compounds, Chuchuhuasi, Cayenne, Maca, and Turmeric.

"Support Immunity" and "Boost Stamina"
"Helps Maintain Joint Health and Flexibility"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"
"Reduces Stress and Frustration"

The ***KemoHerb-1*** has no toxic side effects. It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, mucus discharges, other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***KemoHerb-1*** into a glass cup and swallow entire contents.

Dosage: Take one (1 fl.oz.) fluid ounce.

KemoHerb-1 dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***KemoHerb-1***, please consult your doctor or call the product hot line in U.S.A. at 1(559) 781-0658 or 1(559) 361-0097. Keep out of reach of children. To be kept in a dry and cool place.

- These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 6094, GARDNERVILLE, NV 89460-0800 * U.S.A.
KemoHerb is a Registered Trademark of Golden Sunrise Pharmaceutical, Inc.

KemoHerb™*-2*

Dietary Supplement

WARNING

Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (1 fl.oz.) (491.50mg)		
Serving Per Container: One (1) serving		
Amount Per Serving		**%DV**
Olive leaf extract	84mg	**
Papaya leaf extract	112mg	**
Vinca extract	110mg	**
** Daily Value (DV) not established.		

Other ingredients: solvent, organic compounds, Chuchuhuasi, Cat's claw and Turmeric.

"Promote Bowel Movement"

The ***KemoHerb-2*** has no toxic side effects. It will promote the body's natural cleansing process which may include cleansing effects such as nausea, diarrhea, vomiting, mucus discharges, other possible symptoms a person may experience, may depend on the persons previous health issues which may include headaches, migraines, weakness, muscle aches, joint pain, heart palpitations, inflammation of the throat, excessive bloating, gas, and shortness of breath, which is only temporary at the time that the patient is being treated with ***KemoHerb***. ONLY USE UNDER THE SUPERVISION OF A PHYSICIAN'S CARE.

Administration: Empty entire contents of ***KemoHerb-2*** into a glass cup and swallow entire contents.

Dosage: Take one (1 fl.oz.) fluid ounce.

KemoHerb-1 dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***KemoHerb-2***, please consult your doctor or call the product hot line in U.S.A. at 1(559) 781-0658 or 1(559) 361-0097. Keep out of reach of children. To be kept in a dry and cool place.

- These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 6094, GARDNERVILLE, NV 89460-0800 * U.S.A.
KemoHerb is a Registered Trademark of Golden Sunrise Pharmaceutical, Inc.

ImunStem®

Dietary Supplement

WARNING

Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS		
Serving Size: (0.50ml) (491.50mg)		
Serving Per Container: 50 serving		
Amount Per Serving		**%DV**
Olive leaf extract	260mg	**
Yarrow flower extract	52mg	**
Rosemary extract	63mg	**
** Daily Value (DV) not established.		

Other ingredients: solvent, organic compounds, monoterpene, fatty acid, cassia oil, and yucca.

"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"

Adverse Actions

- In rare circumstances an adverse reaction in the month such as "mild blisters" have occurred.
- A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a benefit response.
- Vomiting.
- Yarrow flowers can cause severe allergic skin rashes.

Administration: Shake bottle well before using and use dropper to place zero point fifty (0.50ml) of ***ImunStem*** under tongue. Leave under tongue for approx. forty (40) seconds and then drink water.

Dosage: Take ½ – ¾ quarter of a dropper, 1-4 times a day, between one (1) and three (3) hours.

ImunStem dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***ImunStem***, please consult your doctor or call the product hot line in U.S.A. at 1(559) 361-0097 or 1(559) 781-0658. Keep out of reach of children. To be kept in a dry and cool place.

- These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 6094, GARDNERVILLE, NV 89460-0800 * U.S.A.
ImunStem is a Registered Trademark of Golden Sunrise Pharmaceutical, Inc.

Aktiffvate®

Dietary Supplement

WARNING

Keep out of reach of children
do not use if safety seal is damaged or missing

SUPPLEMENT FACTS **Serving Size:** (0.50ml) (491.50mg) **Serving Per Container:** 50 serving		
Amount Per Serving		**%DV**
Turmeric extract	175mg	**
Cayenne extract	40mg	**
Eucalyptus extract	20mg	**
** Daily Value (DV) not established.		

Other ingredients: solvent, organic compounds, fatty acid, Wintergreen, Yucca, and Olive leaf.

"Support Immunity" and "Boost Stamina"
"For the Relief of Occasional Sleeplessness"
"Maintains Healthy Lung Function"
"Helps Restore Mental Alertness or Wakefulness when Experiencing Fatigue or Drowsiness"
"Helps You Relax"
"Helps Maintain Cardiovascular Function and a Healthy Circulatory System"

Adverse Actions

- In rare circumstances an adverse reaction in the month such as "mild blisters" have occurred.
- A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a benefit response.
- Vomiting.

Administration: Shake bottle well before using and use dropper to place zero point fifty (0.50ml) of ***Aktiffvate*** under tongue. Leave under tongue for approx. forty (40) seconds and then drink water.

Dosage: Take ½ – ¾ quarter of a dropper, 1-4 times a day, between one (1) and three (3) hours.

Aktiffvate dietary supplement may support immunity, improve overall health for the human body and maintains good well-being.

WARNING: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of ***Aktiffvate***, please consult your doctor or call the product hot line in U.S.A. at 1(559) 361-0097 or 1(559) 781-0658. Keep out of reach of children. To be kept in a dry and cool place.

- These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by: **Golden Sunrise Nutraceutical, Inc.**
P.O. Box 6094, GARDNERVILLE, NV 89460-0800 * U.S.A.
Aktiffvate is a Registered Trademark of Golden Sunrise Pharmaceutical, Inc.

Establishment Inspection Report FEI: **3012327979**
Golden Sunrise Pharmaceutical Inc. EI Start: 2/19/2019
Porterville, CA 93257 EI End: 3/22/2019

TABLE OF CONTENTS

SUMMARY

This initial inspection of Golden Sunrise Pharmaceutical Inc. (GSPI), a dietary supplement manufacturer, was identified in eNSpect as Op ID 11859. It was identified as a SSIL-A firm and inspected in FY2019 in accordance with Compliance Program (CP) 7352.002, Unapproved New Drugs, under PAC63002. CP 7321.008, Dietary Supplements, was not covered.

Form FDA 483, Inspectional Observations, was not issued during the current inspection. It focused on cancer patient treatment under the care of physician with KemoHerbs 1, 2, PI and NR. A total of forty-two patients have been treated since April 2017.

The firm's Kemo Herb 1, 2, PI and NR products are used to treat and cure diseases for patients under the care of physicians. These four products are labeled as dietary supplements.

No refusals were encountered.

Documentary samples 1083657, 1105686, 1105687 and 1105688 were collected to document interstate commerce of Kemo Herbs 1, 2, PI and NR.

AMINISTRATIVE DATA

Inspected firm:	Golden Sunrise Pharmaceutical Inc.
Location:	219 North E Street Porterville, CA 93257
Phone:	559-781-0658

FAX:	559-615-1268
Mailing address:	219 North E Street Porterville, CA 93257
Dates of inspection:	2/19/2019, 2/20/2019, 2/21/2019, 2/22/2019, 3/7/2019, 3/18/2019, 3/22/2019
Days in the facility:	7
Participants:	John A. Gonzalez, Investigator

On February 19, 2019, I presented my Federal Credentials and issued form FDA 482, Notice of Inspection, to Mr. Huu S. Tieu, President. Mr. Tieu stated that he was the most responsible person at the firm.

On February 22, 2019, Mr. Huu S. Tieu, President, signed form FDA 463a, affidavit.

On March 7, 2019, I presented my Federal Credentials and issued form FDA 482, Notice of Inspection, to Mr. Huu S. Tieu, President.

On March 18, 2019, I presented my Federal Credentials and issued form FDA 482, Notice of Inspection, to Mr. Huu S. Tieu, President.

On March 22, 2019, Mr. Huu S. Tieu, President, signed form FDA 463a, affidavit, which was an addendum to his affidavit dated 2/22/2019. This second affidavit was collected to document interstate shipments of Kemo Herbs 1, 2, PI and NR.

A copy of this report and any FMD-145 correspondence should be addressed to:
Mr. Huu S. Tieu, President
Golden Sunrise Pharmaceutical Inc.
219 North E Street
Porterville, CA 93257

HISTORY

Golden Sunrise Pharmaceutical Inc. (GSPI) was incorporated in the state of California on 9/7/2011. The firm's manufacturing operations were located at 560 West Putnam Avenue, Suite 2, Porterville CA 93257 between 2009 and December 2017. However, since December, 2017, its headquarters is located at 219 North E Street, Porterville CA 93257. The firm manufactures dietary supplements, some of which are used to treat patients in various stages of cancer under supervision of the firm's employee, Dr. Stephen R. Meis, M.D.. I observed product labels and small quantities of dietary supplements at this site.

Mr. Tieu provided a list of all related firms and their functions (**Exhibit JAG-1 two pages**). The

following firms are related to GSPI:

EDM Industries Inc. located at 19873 Avenue 216, Strathmore CA 93267

Mr. Tieu and Mr. Martin F. Loeffler, Vice President of GSPI, accompanied me on a tour of this site on 2/20/2019. Mr. Loeffler stated that bulk compounding and encapsulation operations occurred in a large metal shop building while filling and labeling operations occurred in the main house. This site is located about eight miles from GSPI's headquarters.

I observed that the firm was labeling about 16,700 one-fluid ounce bottles of ImunStem, a dietary supplement, identified by batch #GS0000002. Mr. Loeffler stated that the bulk compounding phase occurred in each of two 25-gallon stainless steel (SS) pots and in a separate one 35-gallon SS pot. Mr. Tieu stated that trays were used to encapsulate Kemo Herbs PI and NR.

This site was formerly located at 2278 South Indiana Street, Porterville CA 93257 (mailing address PO Box 8552 Porterville CA 93258). Mr. Tieu stated that he bought this company in 2014.

Golden Sunrise Nutraceutical Inc. located at 202 South Mirage Avenue, Lindsay CA 93247

This firm was incorporated on 3/12/2018 in the state of Delaware. It functions as the sales and marketing division of GSPI. Mr. Tieu stated that it is owned by Dennis L. Hylton, Chief Financial Officer at GSPI. I did not visit this site, which is located about eleven miles from GSPI's headquarters.

Metal building owned by Martin F. Loeffler, Vice President of GSPI located at 20900 Avenue 200, Lindsay CA 93247

Messrs. Tieu and Loeffler accompanied me on a tour of this warehouse storage site. I observed one pallet containing 15,000 units of ImunStem, labeled for Rx only. The firm submitted an application with CBER for ImunStem, one fluid ounce bottles, which are labeled for Rx only. However, GSPI has not distributed or administered this product. GSPI manufactured 16,705 bottles and all units manufactured were accounted for. For example, I observed five pallets; 200 cases per pallet; fifteen bottles per case (15,000) at this site. I observed 111 cases; fifteen bottles per case (1,665) at EDM Industries Inc., 19873 Avenue 216, Strathmore CA 93267. I observed 39 bottles at its Headquarters. I also verified that one bottle was provided as a sample to Sonya Fontana, Nurse Practitioner, at Oak View Medical Group in Visalia CA on 11/7/2018. I verified that none of this product was distributed and all units manufactured were accounted for.

GSPI office hours are Monday through Friday from 8AM – 5PM.

The firm is currently registered with FDA as a drug establishment until 12/31/2019.

INTERSTATE COMMERCE/JURISDICTION

The firm is currently manufacturing and distributing Kemo Herbs 1, 2, PI and NR (Kemo Herb treatment) that are labeled as dietary supplements to patients in various stages of cancer under a physician's care. Mr. Tieu stated that Kemo Herb treatment is administered by a licensed medical doctor and registered nurse, both of which are employed by GSPI. He stated that the public (end users) cannot purchase these cancer treatment products and all patients must be seen by their medical professionals prior to administration.

Mr. Tieu stated that Stephen R. Meis, M.D. was hired as the Medical Director of GSPI in April-May 2017 to screen, diagnose and treat cancer patients with ImunStem and Aktiffvate products labeled as dietary supplements prior to administration of Kemo Herb 1, 2, PI and or NR, which are also labeled as dietary supplements. Prior to this date, Mr. Edgar A. Ayala, Clinical Nurse Consultant, screened, diagnosed and treated patients at different stages of cancer with these six dietary supplements

Mr. Tieu and Dr. Stephen R. Meis stated that these four Kemo Herb dietary supplements were classified as Regenerative Advanced Therapy (RAT) products as listed under Section 361 of the Public Health Service Act and 1271 of Title 21, Code of Federal Regulations. However, Regenerative Therapy Applications have not been submitted for any products.

On 2/19/2019, I observed that the firm was promoting its ImunStem Rx only product labeled with NDC No.: 70642-001-01 on the internet for Serious or Life-Threatening diseases or conditions (**Exhibit JAG-2 pages 1-4**).

Mr. Tieu also provided a copy of an About Us website with a background for Golden Sunrise Nutraceutical and list of physicians that recommend and prescribe his Kemo Herb treatments (**Exhibit JAG-2 pages 5-11**). This list identifies six medical professionals. However, only Dr. Stephen R. Meis, Medical Director, is employed by GSPI. Mr. Tieu stated that Dr. M. George, M.D., Internal Medicine, is not an employee of GSPI, as well as the other four listed persons.

Mr. Tieu also provided its website with the ImunStem label and Prescribing Information (**Exhibit JAG-2 pages 12-23**). It included information for indications and usage; dosage and administration; dosage forms and strengths; contraindications; warning and precautions; adverse reactions; drug interactions; use in specific populations; and over dosage.

Mr. Tieu stated that he submitted an application for ImunStem Rx only with the FDA. However, it was not approved. He stated that none of this product was used to treat any patients. Mr. Tieu stated that ImunStem is also available as a dietary supplement and currently administered with other products, such as Kemo Herb. On 2/20/2019, Mr. Tieu provided a letter stating that he removed ImunStem and NDC No.: 70642-001-01 from their website (**Exhibit JAG-2 page 24**). I verified this on 2/20/2019.

Mr. Tieu provided an Investigator's Brochure for ImunStem, Aktiffvate, and KemoHerbs (Kemo Herbs 1, 2, PI and NR) dated 3/25/2019, including Cancer Survival Rate Results completed on

3/18/2019 written in conjunction with Dr. Meis and Raphael Ayala, Attorney (**Exhibit JAG-3 thirty-nine pages**). This brochure described Kemo Herb treatment and their benefits; product development, including cellular malfunction; Cancer Survival Rate Results; treatment of forty-two cancer patients, including names, diagnoses stage and dates, conventional treatment, and Golden Sunrise treatments; Remarkable Results on 10 of 42 Patients; Longevity only for Golden Sunrise Nutraceutical Therapy; Longevity, Combination of Chemotherapy/ Radiation/ Golden Sunrise Nutraceutical Therapy; and Deceased with Combination of Conventional & Golden Sunrise Nutraceutical Treatments.

Dr. Meis also provided a list of cancer patients treated only with Kemo Herbs; Lost to Follow Up; Deceased; and Alive (**Exhibit JAG-4 two pages**). Informed Consent for Treatment forms were obtained for each cancer patient treated with GSPI dietary supplements. I did not observe any evidence that the firm was performing a formal clinical study for their Kemo Herb products.

As noted in the Investigator's Brochure dated 3/25/2019 above, Mr. Tieu provided copies of its ten of forty-two Remarkable patient's medical records (**Exhibit JAG-5 124 pages**). Patient #10 with initials "JO" was the first cancer patient treated with Kemo Herbs in April 2017. On 4/30/2016, this patient was treated ImunStem (dietary supplement) and Aktiffvate on 4/30/2016. The patient's medical chart was collected (**Exhibit JAG-5 pages 97 to 124)**.

Cancer Patient #6 with initials "HSD" was treated with Kemo Herbs by Mr. Edgar Ayala, Clinical Nurse Consultant at GSPI (**Exhibit JAG-5 pages 40-46).**

An affidavit signed by Mr. Tieu on 2/22/2019 also references the treatment of three cancer patients with Kemo Herbs, which were identified with initials "HSD" patient #6; "JR"; and "GE" (**Exhibit JAG-6 thirty-eight pages**). Mr. Edgar Ayala also diagnosed and treated patients with initials "HSD" and "GE".

Mr. Tieu provided copies of its Primary Plan of Care for ImunStem and Aktiffvate (**Exhibit JAG-7 pages 1-7**) and Cancer Plan of Care for KemoHerb (**Exhibit JAG-7 pages 8-16**). He signed an affidavit dated 3/22/2019 stating that these products are promoted through word of mouth and grass roots efforts as well by visits made to Mexico in 2010; Cambodia in 2011; and China in 2012-2013 (**DOC 1083657 and Exhibit JAG-10**).

On 2/21/2019, I took photographs of a sign on Highway CA-65 North and Avenue 184 in Porterville, CA that read "golden sunrise NUTRACEUTICAL CANCER BREAKTHORUGH KemoHerb" (**Exhibit JAG-8 pages 1-2**).

On 3/7/2019, Mr. Tieu provided a flyer for Jeff O'Neal Remembrance Event at the Visalia Nazarene Church on 3/9/2019 (**Exhibit JAG-8 page 3**). A photograph of Mr. O'Neal shows him with the firm's Cancer breakthrough KemoHerb sign.

Mr. Tieu stated that about 50% of its raw materials are received in interstate commerce and shipped

about 10% of finished products into interstate commerce.

The firm's volume of business is as follows:
$36,000 in 2016
$190,000 in 2017
$580,000 in 2018
$120,000 in January-February 2019

Mr. Tieu provided a handwritten list of English and Latin herbs used in the manufacture of the firm's products (**Exhibit JAG-9 one page**). For example, Chuchuhuasi is also known by the Latin name Maytenus Krukovii and Cat's claw is known as Uncaria Tomentosa or Una de Gato in Spanish.

The following records document the receipt of raw materials and distribution of finished products into interstate commerce:

Documentary sample 1083657 consists of affidavits signed by Mr. Huu S. Tieu, President, of Golden Sunrise Pharmaceutical Inc., on 2/22/2019 and 3/22/2019; Centro Naturista in Mexicali, BC Invoice #'s 001203 dated 4/5/2016 and 001257 dated 4/28/2016 document the purchase of Chuchuhuasi and Graviola, raw materials used in the manufacture of Kemo Herb 1 on 2/3/2017; batch record dated 2/3/2017 for the manufacture of 3,500 one fluid ounce bottles of Kemo Herb 1 lot #KMH0001 with expiration date 2/3/2022, including attached immediate container/carton/shipping carton label (firm uses the same label for all three); EDM Invoice dated 1/25/2017 and labeling showing the manufacture of Chutur-10 (containing Maytenus Krukovii or Chuchuhuasi), Caybigo, and Grama (containing Annona muricata Linn or Graviola) used in Kemo Herb 1 lot #KMH0001; and Invoice #153 dated 11/15/2018 and USPS shipping record dated 11/14/2018 document the sale of two-one fluid ounce bottles of Kemo Herb 1 to Birmingham Royal Oak Medical Group in Royal Oak, MI. Refer to **Exhibit JAG-10 twenty-two pages**. Note: Invoice 153 also shows the sale of two-one fluid ounce bottles of Kemo Herb 2.

Kemo Herb 2 Batch record for lot #KMH00001 dated 2/3/2017, expiration date 2/3/2022, shows the manufacture of 3,500 one fluid ounce bottles. A copy of its immediate container label is attached. The outer carton and shipping carton use the same label. The raw materials Chutur-10 and Pavin were manufactured at EDM Industries Inc. in Porterville CA, both of which were used in Kemo Herb 2. Mr. Tieu stated that the same Chutur-10 raw material used to manufacture Kemo Herb 1 lot #KMH0001 (DOC 1083657) was used in this product. One of Chutur-10s raw materials identified on the label is Maytenus Krukovii or Chuchuhuasi. Mr. Tieu stated that Hector Nungaray, Manager of Packaging and Mixing, traveled to Mexicali, BC in his car to purchase various herbs from Centro Naturista. For example, Centro Naturista Invoice 001203 dated 4/5/2016 shows the purchase of Graviola, Una de Gato and Chuchuhuasi and Invoice 001257 dated 4/28/2016 shows the purchase of Graviola and Chuchuhuasi. Mr. Tieu stated that Pavin contains the herb Uncaria Tomentosa or Cat's Claw (Una de Gato), which was purchased from Centro Naturista. Invoice #182 dated 1/1/2019 and USPS shipping record dated 1/3/2019 document the sale of two-one fluid ounce bottles of Kemo Herb 2 to Birmingham Royal Oak Medical Group in Royal Oak, MI. Refer to **Exhibit JAG-11 eleven pages and Documentary sample 1105686**.

Kemo Herb PI batch record for lot #KMH0001 dated 11/7/2017, expiration date 11/7/2022, shows the manufacture of five pounds of Kemo Herb PI using raw material NutraBlend-KemPI. Mr. Tieu stated that the label attached in the batch record is the same used on the immediate bulk container and bottle of capsules. Mr. Tieu provided a photograph of the bulk 4.5-pound glass container dated 11/7/2017 after encapsulating an unknown number of Kemo Herb PI bottles with twenty-five capsules each. He also stated that an encapsulation batch record was not created. Mr. Tieu provided Sales Order 12685 dated 8/16/2017 from Herbs America, 1065 Messinger Road, Grant Pass, OR 97527 (Mailing address PO Box 446, Murphy, OR 97533) showing the purchase of Chuchuhuasi (Maytenus macrocarpa aka Krukovii), Graviola (Annona Muricata), and Maca Magic (Lepidium Meyenii). These three herbs were used to manufacture Kemo Herb PI lot #KMH0001 on 11/7/2017 by EDM Industries Invoice dated 10/15/2017. A copy of the NutraBlend-KemPI label was provided by Mr. Tieu. Invoice 213 dated 1/25/2019 and USPS record dated 1/17/2019 document the sale of one bottle of Kemo Herb PI containing twenty-five capsules to Birmingham Royal Oak Medical Group in Royal Oak, MI. Refer to **Exhibit JAG-12 eleven pages and Documentary sample 1105687.**

Kemo Herb NR batch record for lot #KMH0001 dated 11/7/2017, expiration date 11/7/2022, shows the manufacture of five pounds of Kemo Herb NR using raw material NutraBlend-KemNR. Mr. Tieu stated that the label attached in the batch record is the same used on the immediate bulk container and bottle of capsules. Mr. Tieu provided a photograph of the bulk 4.5-pound glass container dated 11/7/2017 after encapsulating an unknown number of Kemo Herb PI bottles with twenty-five capsules each. He also stated that an encapsulation batch record was not created. Mr. Tieu was unable to provide purchase records for any raw material herbs used to manufacture this product. Mr. Tieu provided copies of the NutraBlend-KemNR label and manufacturing EDM Industries Invoice dated 10/15/2017. Invoice 213 dated 1/25/2019 and USPS record dated 1/17/2019 document the sale of one bottle of Kemo Herb NR containing twenty-five capsules to Birmingham Royal Oak Medical Group in Royal Oak, MI (**Exhibit JAG-12 pages 10-11)**. Refer to **Exhibit JAG-13 eight pages and Refer to Documentary sample 1105688**.

Mr. Tieu provided the following invoices documenting the purchase of various herbs used in the firm's dietary supplements:

Invoice #25579 dated 10/24/2017 and its Packing Slip dated 10/31/2017 show the purchase of powders Jiaogulan; Periwinkle; Red Root; Witch Hazel; Self Heal; Bilberry Leaf; and Blood Root from Ecuadorian Rainforest LLC, 25 Main Street, Building #6, Belleville, NJ 07109-3010 to GSPI (**Exhibit JAG-14 pages 1-2**);

Invoice #00577886 dated 11/22/2017 shows the purchase of Goldenseal herb powder; Barberry Root Bark powder; and Licorice Root powder from BDS Natural Products, Inc., 2779 El Presidio Street, Long Beach CA 90810 to GSPI (**Exhibit JAG-14 page 3)**; and

Funds Transfer Request Authorization wire date 10/29/2018 shows the purchase of thirty herbs (including Graviola extract #18 and Gout - correct spelling is Gotu Kola #25) as per Proforma

Invoice SY-IN201822075 dated 12/21/2018 from Sciyu Biotech Co., Ltd., 2-21025, I-Building, Tanyan South Road, Xi'An 710065, China to Golden Sunrise Nutraceutical, and Combined Transport Bill of Lading dated 10/12/2018 (**Exhibit JAG-14 pages 4-7**).

The following finished product labels were collected:
Kemo Herb-1; Kemo Herb-2; KemoHerb-NR; KemoHerb-PI; ImunStem; and Aktiffvate (**Exhibit JAG-15 four pages**).

The following raw material herb labels from Sciyu Biotech Co., Ltd., China were collected: Graviola extract powder produce date 12/20/2018; Cats Claw extract powder produce date 10/15/2018; Maca extract powder produce date 10/15/2018; Cayenne extract powder produce date 9/2/2018; and Turmeric extract powder produce date 8/25/2018 (**Exhibit JAG-16 five pages**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Huu S. Tieu, President stated that he was the most responsible person at the firm. He stated that he founded Golden Sunrise Pharmaceutical Inc. in 2009. Mr. Tieu also owns or is a co-owner at EDM Industries Inc. and Golden Sunrise Nutraceutical Inc.

Mr. Tieu provided an Organizational Chart for Golden Sunrise Nutraceutical (**Exhibit JAG-17 one page**). Three employees report directly to Mr. Tieu; namely Mr. Martin F. Loeffler, Vice President; Dennis L. Hylton, Chief Financial Officer; and Dr. Stephen R. Meis, Medical Director.

Mr. Huu S. Tieu, President, is responsible for overseeing all activities and employees. He is directly responsible for product development; regulatory activities and submissions; formulations; labeling; manufacturing of finished dietary supplements, including encapsulation activities using trays; purchasing raw materials (herbs); manufacturing of herb combinations (such as Chutur-10) according to proprietary directions; promoting products; sales and distribution; and record keeping. Mr. Tieu accompanied on all days of the inspection and provided copies of all records described in this report.

Mr. Martin Loeffler, Vice President, is responsible for manufacturing finished dietary supplements and raw materials, including compounding, filling and encapsulation activities; product labeling; and record keeping. Mr. Loeffler has one direct report – Mr. Hector Nungaray, Manager of Packaging and Mixing at EDM Industries in Strathmore CA. Mr. Loeffler also owns a GSPI warehouse located at his ranch, 20900 Avenue 200, Lindsay CA 93247. Mr. Loeffler reports directly to Mr. Tieu.

Dr. Stephen R. Meis, M.D., Medical Director, is responsible for diagnosing and treating cancer patients with Kemo Herbs, ImunStem and Aktiffvate as well as maintaining medical records. He has been employed since April-May 2017. Dr. Meis also has a private practice in the Porterville CA area. Dr. Meis reports directly to Mr. Tieu.

I did not interview Dennis Hylton, CFO. However, Mr. Tieu stated that Mr. Hylton reports directly to him.

I met with Mr. Hector Nungaray, Manager of Packaging and Mixing while touring the manufacturing site, EDM Industries, Inc. located in Strathmore CA. He is responsible for mixing, labeling, and packaging activities. Mr. Nungaray reports directly to Mr. Loeffler.

PRODUCT PROMOTION

Mr. Tieu stated that their products are promoted through word of mouth and grassroots efforts through churches. He also visited Mexico in 2010; Cambodia in 2011; and China in 2012-2013 to promote GSPI products.

I observed a sign promoting the firm's Kemo Herb products on 2/21/2019. I took photographs of it while traveling on Highway CA-65 North and Avenue 184 in Porterville, CA that read "golden sunrise NUTRACEUTICAL CANCER BREAKTHORUGH KemoHerb" (**Exhibit JAG-8 pages 1-2**).

During an internet search, I observed a "Physician" section related the firm (**Exhibit JAG-2 pages 8-9**). Six medical professionals were listed, including Drs. Stephen Meis and Mumtaz George. Mr. Tieu stated that Dr. Meis is an employee of GSPI, and he is responsible for diagnosing, administering Kemo Herb products and caring for cancer patients.

Mr. Tieu stated that Dr. George became aware of GSPI Kemo Herb, ImunStem and Aktiffvate dietary supplements through his word-of-mouth and grassroots efforts. Dr. George has been treating cancer patients with these products at his clinic in Royal Oak, MI.

Mr. Tieu stated that other medical professionals listed under the "Physician" section have also been administering Kemo Herb products to cancer patients. Mr. Tieu stated that on occasion, he visits local hospitals to promote his products and as a result, they are administering Kemo Herb products to cancer patients under their care. These medical professionals include Sonja I. Fontana, F.N.P.; Richard N. Ashden, D.C., Ed.D, C.M.E.; Nikki Arguinzoni-Gil, N.D.; and Professor Dr. Albert M. Hutapea.

Dr. Tieu stated that he was promoting ImunStem labeled with NDC No.: 70642-001-01 on the internet (**Exhibit JAG-2 twenty-four pages**). However, he voluntarily removed this information on or about 2/20/2019 when he admitted that this product had not received approval by the agency.

Mr. Tieu provided a flyer for Jeff O'Neal Remembrance Event at the Visalia Nazarene Church on 3/9/2019 (**Exhibit JAG-8 page 3**). A photograph of Mr. O'Neal shows him with the firm's Cancer breakthrough KemoHerb sign. Mr. Tieu stated that his products are also promoted during events such as this.

FIRM'S TRAINING PROGRAM

The firm does not have a formal training program. Mr. Loeffler stated that he manufactures raw materials and dietary supplements according to Mr. Tieu's directions.

MANUFACTURING/DESIGN OPERATIONS

Manufacturing Site in Strathmore CA

On 2/20/2019, I toured the firm's manufacturing facility, EDM Industries Inc., located at 19873 Avenue 216, Strathmore CA 93267 with Messrs. Tieu and Loeffler. I observed two-25 gallon mixing tanks identified as Tank #1 and Tank #2, as well as one 35-gallon mixing tank identified as Tank #3. Mr. Loeffler provided a copy of the batch record for the manufacture and labeling of 16,705 one-fluid ounce bottles ImunStem, Rx only (**Exhibit JAG-18 pages 1-7**). A sample label was attached to the batch record. The label identified the immediate bottle as "LOT: IS00002 EXP: 10/2023". However, the batch record lacked copies of the package insert, outer carton and shipping carton as well as complete instructions for manufacturing 16,705 fluid ounces in two-25 gallon and one-35 gallon tanks (three tanks account for only 10,880 fluid ounces).

Mr. Tieu provided copies of the immediate bottle label, package insert and outer carton for ImunStem Rx only (**Exhibit JAG-18 pages 8-10).** None of this product has been administered to any patient; all units have been accounted for; and are stored under Mr. Tieu's control.

Kemo Herb Inventory

Mr. Tieu provided the following inventory list for its four Kemo Herb products (**Exhibit JAG-19 one page**):

For example, 3,500 units of Kemo Herb 1 were manufactured; 219 cases (15 units per case) and 5 loose bottles remain; and 53 bottles were sold;

3,500 units of Kemo Herb 2 were manufactured; 219 cases (15 units per case) and 5 loose bottles remain; and 53 bottles were sold;

Eleven loose bottles of Kemo Herb PI, 25 capsules each, were manufactured; fifteen bottles were sold; and

Twelve loose bottles of Kemo Herb NR, 25 capsules each, were manufactured; fifteen bottles were sold.

Mr. Tieu provided photographs of bulk 4.5-pound glass containers dated 11/7/2017 of Kemo Herb PI and NR bulk product **(Exhibits JAG-11 and 12**). Their batch records show that five pounds of these dietary supplements were manufactured.

I asked Mr. Tieu how many Kemo Herb PI and NR capsules can be filled from five-pound bulk product. He stated that 1,677 capsules can be filled from one pound of bulk or five pounds can fill 8,355 capsules.

I also asked Mr. Tieu how many bottles of ImunStem, Aktiffvate, Kemo Herb 1, 2, PI and NR were used to treat all forty-two cancer patients. He provided the following estimates:
250 bottles of ImunStem and Aktiffvate; 95 bottles of Kemo Herbs 1 and 2; and 45 bottles of Kemo Herbs PI and NR.

ImunStem NDA #204701

Mr. Tieu provided a copy of new drug application 204701 for ImunStem, Chemistry, Manufacturing and Controls, dated 7/1/2015 (**Exhibit JAG-20 pages 1-36**). Confidential Statements of Formula and Invoice 32 dated 2/10/2015 shows it contained OVE-60; Yarrow-65 and Rosemary-55, as well as Yucca-70 (ThermX70) (**Exhibit JAG-20 pages 37-46**). No lot numbers were documented for any raw material used during the manufacture of ImunStem.

Mr. Tieu provided copies of the compounding records for bulk ImunStem, lot #A1500001, expiration date April 2018, dated 3/17/2015, which included the immediate container label and Certificate of Analysis (**Exhibit JAG-21 pages 1-5**). The finished product lot number was identified as "IS00001". Refer to ImunStem Testing Records section below for more information. Mr. Tieu stated that a new label was created and affixed to the immediate containers and outer cartons (**Exhibit JAG-21 pages 6-7**). The bulk product was shipped to WePackItAll, 2745 Huntington Drive, Duarte, CA 91010 for filling, labeling and packaging (**Exhibit JAG-21 pages 8-34**).

Mr. Tieu provided copies of a second file titled "IMUNSTEM NDA NO.; 204701 Karen Winestock Division of Anti-Viral FDA", which include correspondence to various FDA personnel **(Exhibit JAG-22 pages thirty-one pages**). Records include National Drug Codes list for ImunStem; Labeler Code 70642; NDA; CDER electronic drug registration and listing; FDA Data Removal Notifications; correspondence to CFSAN; dietary supplement labeling; and National Drug Code Directory information.

ImunStem Dietary Supplement

Mr. Tieu provide copies of his file for ImunStem Dietary Supplement FDA No.: 2015-4196 (**Exhibit JAG-23 thirty-six pages**). Mr. Tieu stated that this dietary supplement version is manufactured in the same manner as the Rx version. Both are available by prescription only and are not available to

the public.

These records include the following:
Notification Letter for Statement on Dietary Supplement (DS) dated 5/26/2015;
ImunStem DS labeling;
Prescription Drug Label;
Package Insert;
Pre-Ind Acknowledgement Letter dated 2/27/2013;
Physician Prescriptions;
Porcaro Charity Fund Brochure; and
CFSAN Notification Letter for Statement on Dietary Supplement dated 5/14/2015

ImunStem Testing Records

The following testing records by Microconsult, Inc., in Carrollton TX were collected for finished product and raw materials (**Exhibit JAG-24 twenty pages**):

Finished product lot IS00002 dated 8/15/2018 shows less than 1 ppm for heavy metals and negative for microbiology;

Finished product lot IS00001 dated 4/25/2015 shows less than 2.5 ppm for heavy metals and less than 1 cfu/Ml FOR Aerobic Plate Count;

Raw material testing for Oleuropein lot A1500001 dated 3/17/2015 showed it met identity testing by FTIR;

Raw material testing for Achillea Millefolium lot B1500001 dated 3/17/2015 showed it met identity testing by FTIR; and

Raw material testing for Rosemarinus Officinalis lot C1500001 dated 3/17/2015 showed it met identity testing by FTIR

KEMO HERBS

I asked Mr. Tieu and Dr. Meis how Kemo Herb treatments worked in the body to increase survival rates of treated cancer patients. Both were unable to provide a scientific explanation. Refer to Investigator's Brochure for ImunStem, Aktiffvate, and KemoHerbs (Kemo Herbs 1, 2, PI and NR) dated 3/25/2019 for background information (**Exhibit JAG-3 thirty-nine pages**).

Mr. Tieu provided Notification Letters for Statement on Dietary Supplements Kemo Herb PI and Kemo Herb NR dated 3/4/2019 (**Exhibit JAG-25 ten pages**). These letters included labels, structure function claims, dosage and warning statements.

Discrepancy Investigations

I did not observe any discrepancies and written procedures captured by the firm. Mr. Tieu stated that he has not investigated any discrepancies.

MANUFACTURING CODES

The firm identities its dietary supplements with a sequential number, item number and expiration date. For example,

Batch #: GSN-000001 refers to Golden Sunrise Nutraceutical, lot #1 (sequential number)
Lot #: KMH0001 refer to Kemo Herb, lot #1 (sequential number)
Item #: KMH-01 refers to Kemo Herb 1
Expiration Date: 2/3/2022 (four-year expiration date)
Refer to **Exhibit JAG-10 page 13**

COMPLAINTS

Mr. Tieu stated that he has not received any complaints. The firm did not have a complaint procedure.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

I did not issue form FDA 483, Inspectional Observations, to Mr. Huu S. Tieu, President. However, I during tours at their manufacturing and warehousing site, I stated that the firm's batch records appeared incomplete; they lacked equipment cleaning and use records; and dietary supplement products did not identify lot numbers on immediate containers, outer cartons, shipping cartons and distribution records.

GENERAL DISCUSSION WITH MANAGEMENT

On 2/22/2019, Mr. Huu S. Tieu, President, was the only person present during the closeout

interview. No objectionable conditions were discussed and form FDA 483 was not issued. Mr. Tieu signed an affidavit dated 2/22/2019.

On 3/22/2019, Mr. Huu S. Tieu, President, was the only person present during the closeout interview. No objectionable conditions were discussed and form FDA 483 was not issued. Mr. Tieu signed an affidavit dated 3/22/2019.

I told Mr. Tieu that I would submit all records collected for a review and classification of his products.

REFUSALS AND SAMPLES COLLECTED

No refusals were encountered.

DOC samples 1083657; 1105686; 1105687; and 1105688 were collected to document interstate commerce of raw materials and distribution of Kemo Herbs 1, 2, PI and NR, respectively.

EXHIBITS COLLECTED

JAG-1 List of related firms (2 pages)
JAG-2 ImunStem internet promotion, network of physicians, prescribing information and removal (24 pages)
JAG-3 Investigator's Brochure dated 3/25/2019 (39 pages)
JAG-4 List of treated cancer patients (2 pages)
JAG-5 Medical Records (124 pages)
JAG-6 Medical Records (38 pages)
JAG-7 Plans of Care (16 pages)
JAG-8 Highway sign photographs and remembrance flyer (3 pages)
JAG-9 List of Herb names (1 page)
JAG-10 DOC 1083657 IS records (22 pages)
JAG-11 Kemo Herb 2 manufacturing records (11 pages)
JAG-12 Kemo Herb PI manufacturing records (11 pages)
JAG-13 Kemo Herb NR manufacturing records (8 pages)
JAG-14 Herb purchase records (7 pages)
JAG-15 DS Labeling (4 pages)
JAG-16 Herb labels (5 pages)
JAG-17 Organizational Chart (1 page)
JAG-18 ImunStem batch record and labels (10 pages)
JAG-19 Inventory (1 page)
JAG-20 ImunStem NDA (46 pages)
JAG-21 Batch records for ImunStem (34 pages)
JAG-22 ImunStem FDA correspondence (31 pages)
JAG-23 ImunStem Dietary Supplement file (36 pages)

JAG-24 ImunStem testing records (20 pages)
JAG-25 Kemo Herb PI and NR Dietary Supplement Notification Letters (10 pages)

ATTACHMENTS

Form FDA 482, Notice of Inspection, issued to Mr. Huu S. Tieu, President, on 2/19/2019 (3 pages)

Form FDA 482, Notice of Inspection, issued to Mr. Huu S. Tieu, President, on 3/7/2019 (3 pages)

Form FDA 482, Notice of Inspection, issued to Mr. Huu S. Tieu, President, on 3/18/2019 (3 pages)

Form FDA 463a, Affidavit, signed by Mr. Huu S. Tieu, President, on 2/22/2019 (2 pages)

Form FDA 463a, Affidavit, signed by Mr. Huu S. Tieu, President, on 3/22/2019 (5 pages)

DOC CRs 1083657; 1105686; 1105687; and 1105688

John A. Gonzalez -S

Digitally signed by John A. Gonzalez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300058412, cn=John A. Gonzalez -S
Date: 2019.04.16 10:32:02 -07'00'

John A Gonzalez, Investigator
ORA/OPQO/DIVISION IV

Golden Sunrise NUTRACEUTICAL
P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658
Fax No.: 1.559.615.1268

1.0 PATIENT INFORMATION

Patient Name: [redacted]
Date of Birth: [redacted]
Sex: Male
Address: [redacted]
Phone Number: [redacted]
Ethnicity: Caucasian
Product: ***METABOLIC Plan of Care***
Date of Product:

Indication: ***Parkinson's Disease***

Referring Physician: None

Physician: Stephen R. MEIS, M.D., Board Certified
219 North E Street, PORTERVILLE, CA 93257
Phone No.: 1.559.901.0975

2.0 BACKGORUND

[redacted] is a 62-years-old white male diagnosed with Parkinson's disease in January 2018. [redacted] was treated by a neurologist and followed by his primary care physician. [redacted] is very healthy and was routinely running long distance weekly, or more often, in a club for many years until he developed the Parkinson's disease. [redacted] never required any medications prior to this except early in 2017for pneumonia, then later in 2017 for Valley Fever. [redacted] failed three (3) Parkinson's medications prescribed by the neurologist: ***Nupro***® patch, ***Sinemet***®, which made him feel bad, and ***Requip***®, which caused a lot of leg edema requiring diuretic treatment.

3.0 SUMMARY

[redacted] started the ***METABOLIC Plan of Care*** with ***ImunStem*** and ***Aktiffvate*** on 05/06/2019. tremors were gone by next follow-up call on 05/21/2019. [redacted] continued the ***ImunStem*** and the ***Aktiffvate*** daily throughout the recommended detoxification sessions of the ***METABOLIC Plan of Care***. [redacted] proceeded with eight (8) detoxification sessions with ***DetoxHerb-1*** and ***DetoxHerb-2***, on 05/31/2019, and 06/16/2019; ***Detox-Herb-PI*** and ***DetoxHerb-NR*** on 07/02/2019 and 07/21/2019; ***AnterFerron-1*** and ***InterFerron-2*** on 08/18/2019; ***C_RProtein*** on 09/15/2019; ***HyProtein-1***, ***HyProtein-2***, ***HyProtein-3***, and ***HyProtein-4*** on 10/16/2019; and lastly ***LyProtein*** on 10/26/2019. While following the patient through all of these sessions, he would notice some tremoring return, but only mildly at times, especially when stressed. [redacted] posture improved from being stooped over, his walking was easier and with

smoother. He was able to bicycle and use weights. [redacted] had done heavy metal testing with another care provider before using the ***METABOLIC Plan of Care***, and he reported that the levels dropped. [redacted] was recommended to continue using the ***ImunStem*** and ***Aktiffvate***, but he uses it intermittently. The last contact with the patient on 10/15/2020, he was still doing great with no rigidity and rare tremoring. [redacted] is extremely happy with his much improved Quality of Life since the pharmaceutical prescription medication gave no benefit and only miserable **side-effects**. Other Golden Sunrise Nutraceutical dietary supplement products supplied during the ***METABOLIC Plan of Care*** were ***C-Nite*** and ***NuerRon***.

4. ATTACHMENT

[redacted] **Testimonial Letter**

Sincerely,

Stephen Meis

Stephen R. MEIS, M.D., Board Certified
Medical Director.

December 29, 2020
Date

To Whom it May Concern,

My name is [redacted] I am a male age 64. I want to share my experiences and results using Golden Sunrise Nutraceutical products. In January of 2018 I was diagnosed by a neurologist, with Parkinson's Disease. In the year prior to this diagnosis I had pneumonia and valley fever (2017). My immune system was obviously weakened. During the spring of 2018 I was tested for toxicity (heavy metals), and the results showed that I was high in some metals (for example: mercury, lead and cadmium). In January when I was diagnosed I was prescribed Neupro. In the early fall I was also prescribed carbidopa-levodopa along with the Neupro, since I had not experienced any improvement. I felt worse with the carbidopa-levodopa. So in late fall I discontinued using it and it was replaced with another medication called requip. This didn't help at all. In fact a side effect of requip is swelling in the lower extremities. I experienced this side effect as my lower legs and feet swelled severely, especially the left foot. The swelling caused a tendon to separate and my big toe on my left foot goes inward. This has resulted in two foot surgeries, October 2019 and February 2020. Neither tendon transfer has worked so I will have ai third foot surgery soon, this time fusing to correct the problem. In May of 2018 I began using products from Golden Sunrise Nutraceutical. I began with Imunstem and Aktivate and eventually added the use metabolic herbs detoxification in order to rid my body of the toxic metals. I immediately noticed a decrease in the hand tremors. They became less frequent and had less intensity. After approximately three months I began adding the metabolic herbs. Tests (urine tests through Doctors Data, using a provoking agent) later showed a decrease of toxic metals in my body.

I have experienced success with the products from Golden Sunrise Nutraceutical. My immune system is strengthened as I have had no illness since the pneumonia and valley fever in 2017. Physically, I feel great and exercise daily utilizing weights, bands and tubing, walking, biking and flexibility training. Tremors are infrequent and my energy level is high. I am thankful to Golden Sunrise Nutraceutical for their products and the improvement in my well being.

Thank you,

[redacted]

Huu Tieu
edrls@fda.hhs.gov
You forwarded this message on 5/18/2018 10:48 AM

May 18, 2018

Drug Registration and Listing Staff
FDA/CDER/Office of Compliance

RE: Labeler Code 70642

Dear Drug Registration and Listing Staff

Please find enclosed the attachments IMUNSTEM information you requested.

If you have any questions, please do not hesitate in giving me a call direct number **1.559.361.0097**. Thank you.

Huu S. TIEU
Golden Sunrise Pharmaceutical, Inc.
P.O. Box 510
PORTERVILLE, CA 93258
Phone No.: 1.559.781.0658

Labeler Code 70642

Product Name: IMUNSTEM		
Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OLEUROPEIN (UNII: 204553545L)	**OLEUROPENIN**	260 mg in 1 ml
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	**ACHILLEA MILLEFOLIUM**	52 mg in 1 ml
ROSEMARY (UNII: IJ67X351P9)	**ROSEMARY**	63 mg in 1 ml
SARSAGENIN (UNII: CFS802C28F)	**SARSAGENIN**	50 mg in 1 ml
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	**CHINESE CINNAMON OIL**	2.6 mg in 1 ml

Packaging

#	Item Code	Packaging Description	Marketing Start Date
1	NDC: 70641-001-01	1 in 1 CARTON	07/01/2018
1		30 ml in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IMUNSTEM® safely and effectively. See full prescribing information for IMUNSTEM.

IMUNSTEM® for oral use, liquid

IMUNSTEM (olive leaf, yarrow flowers, rosemary leaf, yucca plant and cassia oil) liquid for oral solution use.

----------INDICATION AND USAGE----------

IMUNSTEM stimulates the immune system throughout the body. (1.0)

----------DOSAGE AND ADMINISTRATION----------

The recommended dosage is in liquid form orally taken ½ to ¾ quarter of a dropper, 1 to 4 times daily. (2.0)

----------DOSAGE FORMS AND STRENGHTS----------

Liquid form – use dropper: ½ to ¾ quarter of a dropper. (3.0)

----------CONTRAINDICATIONS----------

There are no contraindications for IMUNSTEM. (4.0)

----------WARNINGS AND PRECAUTIONS----------

IMUNSTEM should be taken only as prescribed and monitored by Qualified medical personnel. IMUNSTEM has been observed to increase the pulse rate and induce vomiting for individuals on rare occasion taking higher dosages of IMUNSTEM. (5.0)

----------ADVERSE REACTIONS----------

- In rare circumstances an adverse reaction in the mouth such as "mild blisters".
- A burning sensation in the throat in the beginning of oral treatment may occur but subsides. If the burning sensation persists, capsules may be substituted for an improved toleration of administration. (6.0)

To report SUSPECTED ADVERSE REACTIONS, CONTACT Golden Sunrise Pharmaceutical Incorporation at 1-559-781-0658 or FDA at 1-800-463-6332 or www.fda.gov/medwatch

----------DRUG INTERACTIONS----------

IMUNSTEM has been combined with other drugs, but has not been thoroughly tested with significant combinations yet to show interactions with multiple combinations. You should always read product labels. (7.0)

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: IMUNSTEM has not been tested on pregnant women. (8.0)

See 17 for PATIENT COUNSELING INFORMATION

01/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the Full Prescribing Information are not listed.

FULL PRESCRIBING INFORMATION

1.0 INDICATIONS AND USAGE

ImunStem stimulates the immune system throughout the body. ***ImunStem*** aids in the cellular regeneration of damaged areas of the body through diseases and injuries. ***ImunStem*** also helps blood flow through the system especially in difficult regions such as body capillaries. ***ImunStem*** is a highly mobile compound that has been shown as a central nervous system and immune system stimulant.

ImunStem can act alone safely or with other medical therapies to maximize efficacy and produce faster and lasting benefits to treat ***Serious or Life-threatening*** diseases or conditions by supporting immune system function. Physicians have observed that using ***ImunStem*** provokes a significant response, i.e., a reduction in symptoms in patients with these diseases: autism, alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, parkinson's, schizoaffective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer. ***ImunStem*** has been shown to help reduced loss of blood from surgical wound and menstrual periods (shorter and lighter periods).

2.0 DOSAGE AND ADMINISTRATION

Take ½ to ¾ of a dropper of ***ImunStem*** under tongue one to four times daily. Leave under the tongue for approximately forty (40) seconds and then drink water.

If the patient has a sensitivity of the mouth and/or throat then an administration orally mixed with one (1) teaspoonful of yogurt or capsules can be administered.

The recommended dosage interval for ***ImunStem*** is between two (2) and three (3) hours when used in ***Serious or Life-threatening*** diseases or conditions and emergency situations, and it is strongly advised that four (4) doses of ***ImunStem*** be taken per day until a medical professional that is monitoring the illness finds it warranted to reduce the dosage interval.

ImunStem **is effective at ½ to ¾ of a dropper 1 – 4 per day:**

Product	Dosage per day	Per Dose Size of a Dropper
ImunStem	1 – 4	½ to ¾

3.0 DOSAGE FORMS AND STRENGTHS

ImunStem **is liquid form:**

Product	Per Dose Size
ImunStem	1.0 ml

Active Ingredients (mg) per Dose of *ImunStem*:

Active Ingredients	mg
Olive leaf extract	260
Yarrow flowers extract	52
Rosemary leaf extract	63
Yucca plant extract	50
Cassia oil	2.6
Total:	427.6

4.0 CONTRAINDICATIONS

There are no contraindications for ***ImunStem***.

5.0 WARNING AND PRECAUTIONS

ImunStem should be taken only as prescribed and monitored by qualified medical personnel. ***ImunStem*** has been observed to increase the pulse rate and vomiting in individuals on rare occasions if taking excessive/higher dosages of ***ImunStem***. Physicians should advise their patients administered ***ImunStem*** that a mild fever may occur, typically this condition can last for one (1) to two (2) days then subsides.

ImunStem should only be taken under a doctor's supervision. The formulation creates high energy levels in patients with ***Serious or Life-threatening*** diseases or conditions and low immune system levels. Patients should not engage in any activity greater than they can tolerate after taking ***ImunStem***. Also, ***ImunStem*** should not replace any existing medication that is prescribed by the primary physician. Only the prescribing physician should alter, modify or update any medications taken by the patient.

Patients interested in changing their medication regimen should consult their physician before modifying any prescribed medication program.

6.0 ADVERSE REACTIONS

- In rare circumstances an adverse reaction in the mouth such as mild blisters have occurred.
- A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a beneficial response.
- Vomiting.
- Yarrow flowers can cause severe allergic skin rashes.

7.0 DRUG INTERACTIONS

ImunStem has been combined with other drugs, but has not been thoroughly tested with significant combinations yet to show interactions with multiple combinations. You should always read product labels. If you have a medical condition, or are taking other drugs, herbs, or dietary supplements, you should speak with a qualified healthcare provider before starting a new therapy.

8.0 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

ImunStem has not been tested on pregnant women. It is recommended that consultation with a health professional be sought before use of ***ImunStem***.

8.2 Nursing Mothers

ImunStem is not recommended for nursing mothers.

8.3 Pediatric Use

ImunStem is not recommended for pediatric patients.

10.0 OVERDOSAGE

Excessive doses of ***ImunStem*** may cause reactions with a cause a variety of symptoms from central nervous system stimulation to damage of the heart, liver and kidneys in extreme overdosing situations. Please refer **5.0 Warning and Precautions.**

Possible side effects may include vomiting, nausea, diarrhea, constipation, dry mouth, dilated pupils, gastrointestinal discomfort, irritations, flushing, and cold sores.

No cases of ***ImunStem*** overdose have been reported.

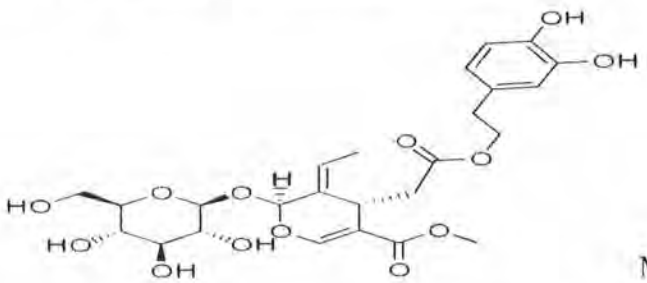
11.0 DESCRIPTION

Golden Sunrise Pharmaceutical Incorporation (Golden Sunrise) is currently marketing ***ImunStem*** dietary supplement product that is comprised of Olive leaf extract, Yarrow flowers extract, Rosemary leaf extract, Yucca plant extract and Cassia oil under the dietary supplement guidelines. ***ImunStem*** is developed as a drug product for treatment of ***Serious or Life-threatening*** diseases or conditions. Based upon the information provided, at least fifty (50) patients with ***Serious or Life-threatening*** diseases or conditions (Autism, Viral diseases, Cancer, Hypertension, Epilepsy/Seizure, Thalassemia Major B, Stroke, etc.) have received treatment with ***ImunStem*** dietary supplement.

ImunStem is an herbal (botanical) drug substance that provides a stimulation effect of the immune system throughout the body to support human health and overall health. ***ImunStem*** aids in the cellular regeneration of damaged areas of the body from diseases and injuries, such as surgical mitigation and bleeding. ***ImunStem*** also helps blood flow through the system especially in difficult regions such as body capillaries. ***ImunStem*** is a highly mobile compound that has been shown as a central nervous system and immune system stimulant.

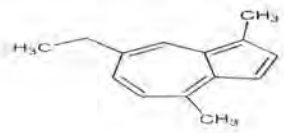
ImunStem can act alone safely or with other medical therapies to maximize efficacy and produce faster and lasting benefits to treated subjects by supporting immune system function.

Oleuropein is component of ***ImunStem*** is chemically described as 4S,5E,6S)-4-[2-[2-(3,4-dihydroxyphenyl)ethoxy]-2-oxoethyl]- 5-ethylidene-6-[(2S,3R,4S,5S,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)- 2-tetrahydropyranyl]oxy]-4H-pyran-3-carboxylic acid, methyl ester. Molecular formula $C_{25}H_{32}O_{13}$ and structure formula as following:



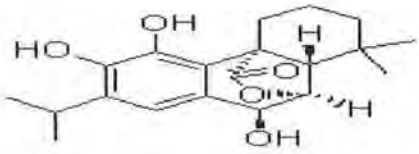
M.W. = 540.514

Achillea Millefolium is component of ***ImunStem*** is chemically described as 7-Ethyl-1,4-dimethylazulene. Molecular formula $C_{14}H_{16}$ and structure formula as following:



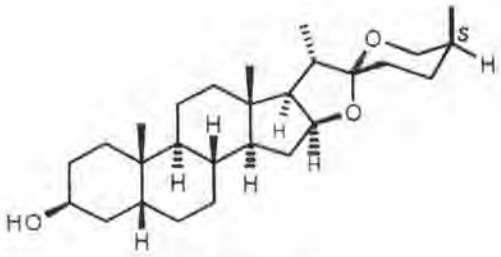
M.W. = 184.28

Rosmarinus Officinalis is component of ***ImunStem*** is chemically described as [4aR-(4aa,9b,10a,10ab)]-1,3,4,9,10,10a-Hexahydro-5,6,9-trihydroxy-1,1-dimethyl-7-(1-methylethyl)-2H-10,4a-(epoxymethano)phenanthren-12-one. Molecular formula $C_{20}H_{26}O_5$ and structure formula as following:



M.W. = 346.42

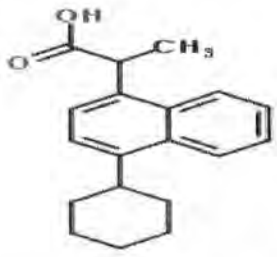
Sarsasapogenin Glycoside is component of ***ImunStem*** is chemically described as 3-O-{[O-α-D-galactopyranosyl(1 → 2)]-[-O-β-D-galactopyranosyl(1 → 6)]-O-β-D-glucopyranosyl-(1 → 4)-β-D-glucopyranosyl}-(25S), 5 β-spirostan-3β-ol. Molecular formula $C_{27}H_{44}O_3$ and structural formula as following:



Sarsasapogenin

M.W. = 416.64

Cassia Oil is component of ***ImunStem*** is chemically described as 2-methoxy-4-prop-2-enylphenol; [(E)-prop-1-enyl]benzene. Molecular formula $C_{19}H_{22}O_2$ and structural formula as following:



M.W. = 282.37678

Inactive ingredients: d-Limonene, 2-Butoxyethanol, Benzenesulfonic acid, C10-16-alkyl derivatives, compounds with 2-Propanamine, Hydrocarbon and water.

12.0 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ImunStem is an herbal (botanical) product, which has pathogenesis and homeostatic properties. ***ImunStem*** is taken in liquid oral doses for internal use. The component of the drug substance that makes the compound of ***ImunStem*** comprises the extraction of ingredients from Olive leaf, Yarrow flowers, Rosemary leaf, Yucca plant, and Cassia oil. The variety of components encompassing these botanicals has a wide use which provides antioxidant activity and a powerful positive effect on the immune system. ***ImunStem*** allows the active ingredients to disperse throughout the body and blood stream; it also has a direct effect upon immune-cell and cellular functioning.

ImunStem has immunostimulating properties in-vivo studies testing patients treated, increasing phagocytic activity and synthesis of helper cell function. ***ImunStem*** has shown to enhance Deoxyribonucleic Acid (DNA) repair before, during, and after chemotherapy drugs, toxic exposure, and chemical-induce damage. ***ImunStem*** modulates anxiety, initially including and then reversing these effects after long-term administration.

ImunStem can play an integral role in hypothalamic activity, easing both parasympathetic and sympathetic nervous systems towards a state of homeostasis. Since blood pressure level is directly linked to the sympathetic nervous system, the lower blood pressure levels exhibited following administration of ***ImunStem*** is compatible with the stabilization of sympathetic nervous system activity. The pulmonary benefits observed are likely due to the focus of deep breathing, this places less pressure on lungs and increases lung capacity, as well as overall improvement seen in breathing efficiency. ***ImunStem*** reduces inflammation by affecting immune responsiveness through neuroendocrine factors. Its positive effect on balance is attributed to the improved use of vestibular input and wider stances.

12.2 Pharmacokinetics

ImunStem is readily absorbed into soft tissue matter when taken as an oral dose. This is accomplished because ***ImunStem*** readily passes through membrane tissue by passive diffusion penetrating to the circulatory system.

ImunStem is a fast acting substance. Once the onset of action takes place patients can notice calmness, improved breathing, mental clarity, and alertness immediately.

It is postulated that in arresting abnormal cellular mutation, the precursors for normal and enhanced cellular regeneration and cellular division can be accelerated in relation to the selective existing disease pathology. Observations of in-vivo testing that display the ability for ***ImunStem*** components to dissolve in hydrophilic substances propose that in the finished chemical form of the product and with its unique makeup, ***ImunStem*** produces a bipolarity that facilitates molecular diffusion through various permeable and selective membranes. It is therefore theorized that the combination of the bodies' thermal energy particularly during variance mutation and inflammatory processes, potentiates the self-propelling of molecules by possible passive membrane transportation or passive diffusion of the ***ImunStem*** compound intact to cross the blood brain barrier also displaying lipophilicity (or lipophilic quality) to retain efficacy and activity for the central nervous system.

In-vivo studies involving treated test subjects have immune system activity in tests including blood tests and have provided the efficacious ability to improve immune system function while maintaining the cellular structure to tissue intact. These studies also reveal that ***ImunStem*** continues to provide improved immune system function with long term use.

13.0 NONCLINICAL TOXICOLOGY

13.1 Genotoxicity

PURPOSE: The purpose of this study is to evaluate ***ImunStem*** for its ability to induce reverse mutation at the histidine locus in *Salmonella Typhimurium* tester trains both in the presence and absence of an exogenous mammalian metabolic system (S9) containing microsomal enzyme.

CONCLUSION: Under the test conditions in this study, ***ImunStem*** was not mutagenic in the tested strains of the *Salmonella typhimurium*, histidine auxotrophs TA97, TA98, TA100, TA102 and TA1535 both in the presence and absence of metabolic activation system. The results indicated that, at the dose concentration of a 25-fold dilution to a 15,625-fold dilution of original liquid, 100µl/plate, ***ImunStem*** did not induce point mutations by base substitutions and/or frame shifts in the genome of these tested strains.

14.0 RESULTS OF PATIENTS AFTER TREATMENT

A small group of patients with ***Serious or Life-threatening*** diseases or conditions found that ***ImunStem*** dietary supplement improved the immune system and alertness immediately.

Physicians have observed that using ***ImunStem*** provokes a significant response, i.e., a reduction in symptoms in patients with these diseases: autism, alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, parkinson's, schizoaffective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer. ***ImunStem*** has been shown to help reduced loss of blood from surgical wound and menstrual periods (shorter and lighter periods).

Fifty (50) patients test subjects administered ***ImunStem*** dietary supplement over the course of time from a few weeks up to three (3) years were made and included observations from attending physicians, nursing staff, care givers and Golden Sunrise medical personnel. Blood reports were also included and medications (if any) were documented. The observations compiled from family physicians and specialists were entered and compared with observations by Golden Sunrise medical staff.

Safety was monitored and throughout these studies no adverse side-effects were noticed. A representative number of test subjects were diagnosed with ***Serious or Life-threatening*** diseases or conditions that required close monitoring by both the attending physician, specialist of that field and by Golden Sunrise medical staff.

a) J.W. is a 10-year-old white male who began treatment with physician psychiatrist in Visalia California when he 6-year-old. He has been diagnosed with fragile-X syndrome. He was diagnosed as Attention Deficit Hyperactivity Disorder (ADHD) (F90.1), and Intermittent Explosive Disorder (IED) (F63.81). He has been treated over the years with Tegretol, Vyvanse, Zoloft, Risperdal; he had a trial at another medical center of R Baclofen. Psychiatrist have also treated him with Gabitril, and Nudexta. He was taking Zoloft 150mg in the morning, Risperdal 1mg at bedtime, and Vyvanse 40mg in the morning.

In July 07, 2016 he was started ***ImunStem*** twenty (20) drops twice a day was started at that point in time. On July 25, 2016 his mother reports as of this date that he is more focused and calmer. His level of perseveration has decreased dramatically. His mother stated that the other day he was organizing the DVDs player in their home and "that's not like him."

b) S.W. is a 64-year-old, white male, who began treatment with psychiatrist when he was 57-year-old. He was initially diagnosed as anxiety disorder Not Otherwise Specified (NOS) (F41.9) and ADHD without hyperactivity (F90.0). Stimulant medication was not effective in treating his focusing problems so Wellbutrin was used. Chlorazepate was used to help with his anxiety. He did well on this combination of medicines until November 2014. He was diagnosed at that point in time as having diabetic neuropathy and was treated with Lyrica. He complained at

that point in time that the medicine made him feel "fuzzy" and he was unable to be productive at work. In February 2015 he stopped the Chlorazepate because he was afraid of having Alzheimer's disease and decreased the Wellbutrin on his own to decrease the fuzziness. He did restart the Chlorazepate eventually. In April 2016 he was taking Cymbalta 60mg in the morning and Ambien 10mg at bedtime. His family doctor had stopped the Wellbutrin and Chlorazepate. He was being treated at that point in time with methadone and Lyrica. He complained again of feeling fuzzy, tired, and unable to do his work.

In July 2016 he was started with ***ImunStem*** twenty (20) drops twice a day. He reported two and half (2-1/2) weeks later that he had more energy and motivation. He was more productive and able to do his work and his pain had been reduced by thirty (30%) percent.

c) S.R. is a 39-year-old white male, who was first seen when he was 28-year-old. He was transferred from another physician and was taking Wellbutrin-SR 100mg three (3) times a day, Clozaril 600mg at bedtime, Zoloft 200mg in the morning, Topamax 100mg at bedtime, and Aricept 20mg at bedtime. He had a significant history of substance abuse, including marijuana, crack cocaine, mushrooms, and acid between the ages of seventeen and 17 & 21-year-old. He was diagnosed as schizoaffective disorder (F25.9) and Polysubstance abuse. He was treated with multiple medications over the years to try to help reduce his psychotic symptoms and increased his sociability. In June 2016, he was taking Vraylar 6mg in the morning, Fanapt 6mg twice a day, Nudexta 20-10 twice a day, Chlorazepate 30mg at bedtime, Prozac 40mg in the morning, Clozaril 300mg at bedtime, Abilify 30mg in the morning, and Gabitril 4mg at bedtime.

In July 07, 2016 he was started with ***ImunStem*** twenty (20) drops twice a day were started at that point in time. He returned on July 21, 2016, reporting that he had decreased the Chlorazepate to 15mg at bedtime, his Prozac had been increased to 60mg in the morning and he had been on ***ImunStem*** for two (2) weeks as well as the other medications listed above. He reported "my brain can keep up with my mind". He stated "my brain is aware of my body". He reported increased energy, clearer thoughts, and non-racing thoughts. He also reported that he had a dry patch of skin on the back of his head that was now gone.

d) L.H. is an 86-year-old, white female, who is diagnosed as having Alzheimer's disease and lives in a skilled nursing facility. She is on a liquid diet, sleeps most of the time, is confined to a wheelchair or a moving bed, and has intermittent episodes of agitation and flat facies. She was treated with ***ImunStem*** ten (10) drops twice a day for two and half (2-1/2) weeks. Both staff and family report that she is less agitated, more alert and is smiling.

After thirty (30) days on ***ImunStem*** the nurses' report there are no longer any agitated episodes. Skilled nursing report that she spends more time awake. On exam, the patient opened her eyes and focused on my face. There was no facial expression, but patient appeared to try and move her lips as if she wanted to talk. (This was a new behavior). When I asked her to move her finger if she could understand me, she did.

e) M.B. is a 69-year-old white male who has been treated for chronic Lymphocytic Leukemia for the last five (5) years. He started taking ***ImunStem*** twenty (20) drops twice a day in October 2015. This was because of the concern of falling red blood cell counts and platelet counts. His white blood cell count, though elevated remained elevated and fluctuant. In October 2015, his red blood cell was four point zero five (4.05) and his platelet count was ninety (90). On April 2016 his red blood cell count was four point nineteen (4.19) and his platelet count was one hundred and five (105). It was felt that this was a significant increase in both his red blood cell count and platelet count. Please see table below as following:

Comparison RBC Count and Platelet Count from October, 2015 through April, 2016

DATE	RBC Count	Platelet Count	
October, 2015	4.05	90	Before ***ImunStem***
April, 2016	4.19	105	After ***ImunStem***

f) R.B. is a 62-year-old white male who was first evaluated on August 19, 2016. He is taking Actos, Metformin, Lorstan, and Travastin for diabetes mellitus, high blood pressure, and glaucoma. There is no history of past substance abuse. He was interested in trying ***ImunStem*** to see if would make any difference with his medical problems. He also complains of mild symptoms of depression including anergia, lack of motivation and feeling depressed about his physical problems. He was diagnosed as depressive disorder NOS and started on ***ImunStem*** twenty (20) drops twice a day.

Patient reported after eight (8) weeks of ***ImunStem*** treatment that his energy and motivation have been increased. He also reported that he was feeling less depressed. He reported that he was able to tolerate higher loads of carbohydrates without changing his diabetes medications, which also affect directly his energy and motivation.

g) J.O. is a 45-year-old white male diagnosed with advanced stage four (4) colon cancer. He was diagnosed in January 2016 and was not thought by the attending physician that he could have a positive outcome as the cancer was in mastitis and had spread throughout his body. His symptoms included a damaged liver, renal obstruction, lung polyps, anxiety, depression, and severe lack of energy. The patient received first cycle of chemotherapy on March 2016.

In April 2016 the patient received his first dose of ***ImunStem*** administered orally at forty (40) drops three times daily. At this time the patient showed noticeable improvement of overall health in minutes. The patient showed an improvement in energy levels as the next day he was playing basketball, mental focus, depression and anxiety improved noticeably and his outlook on life is a positive hope. His tumors have shrunk and since the treatments of ***ImunStem*** and chemotherapy he has had no major side-effects such as hair loss, debilitating constipation, depression, anxiety, weight loss, or nausea. He has not had to visit emergency for complications except for a staph infection at his injection port. Patient is doing well and can function without interference to his normal lifestyle. The patient has been motivated to tell others of the benefits of taking ***ImunStem*** that it can help others in ***Serious or Life-threatening*** conditions.

h) J.A. is a 2½-year-old male that was diagnosed with Autism/Seizure. His symptoms included, seizure, drooling, hyperactivity, disorientation, lack of pain stimuli, poor communication skills and uncontrollable outbursts. He was diagnosed in October 2016 and was considered near the highest level of Autism that provided government programs to assist with his mental state. He has an unknown regimen of prescription medications and government assistance is provided for re-education of motor skills.

In December 2016 he began oral administration of ***ImunStem*** at two (2) drops per 12-fluid-ounces of milk. In about four (4) days was noticed by the parents that he was aware of his surroundings and responded to the parents' direction. He was also noticed to stop drooling and felt pain in normal situations (such as falling down while playing). He also began to have a reduction in seizures. He has improved where there are no known seizures being observed at this time and he is more responsive to direction, his drooling has not returned and he is beginning to act as a normal 2½-year-old.

i) S.R. is a 62-year-old black male that was diagnosed with advanced stage Parkinson's disease. He was diagnosed 4-year-ago and has had a steady progression of the Parkinson's disease. The symptoms include, slurred speech, an unsteady (uneven) gait, memory loss, depression, tremors and occasional falling. He has taken the prescribed medication which had only intermittent results.

In April 2015 he began taking ***ImunStem*** oral administration at thirty (30) drops twice a day. He states that he feels more stable as he can walk on his own, has no more falling episodes, can focus better (clearer thought), has reduced tremors and has significantly reduced his depression. He has also returned to his previous employment.

j) R.W. is a 16-year-old female that has excessive menstrual bleeding and long painful menstrual periods since 2013. She took Vicodin every month on the first day of her period. She had debilitating pain that interfered with her lifestyle and activities and kept her confined to her home.

In October 2016 she began taking ***ImunStem*** oral administration at thirty (30) drops per day. After three (3) weeks her menstrual bleeding reduced greatly and her pain had been alleviated. Her period duration had dropped by half and she is able to function in public as a normal.

k) R.G. is a 60-year-old male diagnosed with an enlarged prostate. He had been to multiple medical professionals that have treated him for everything from bleeding eye to heart attack. Physicians have recommended various surgeries for his prostate but the patient did not want to have these surgeries because of the possible adverse outcomes.

In October 2017 he was administered ***ImunStem*** while in the hospital being treated, within three (3) minutes he felt an improved feeling to his prostate which felt like less pressure and less pain. He continued to improve over four (4) months and no longer requires invasive procedures to alleviate prostate swelling. Please see table below as following:

Comparison eGFR, WBC and Platelet Count from October, 2017 through December, 2017

DATE	eGFR	WBC Count	Platelet Count	
October, 2017	15	6.36	136	Before ***ImunStem***
December, 2017	40	8.00	332	After ***ImunStem***

l) E.B. is a 46-year-old white male was diagnosed with Multiple Sclerosis (MS) in November 2016. He was first suspect as having lime disease but upon further testing it was found to be MS. He experienced a continual degradation of motor function until he was bedridden, he had almost total immobility of his legs and arms. The caregiver would assist the patient for all movement including bathroom activities.

Patient began taking ***ImunStem*** in October 2017 and showed positive response for the first dose. Over the course of treatments the patient has experienced improved motor function to where he can sit in a wheelchair and move himself and can sit on the toilet without the aid of the caregiver. The patient continues to show marked improvement as the treatment progresses. The see table below as following:

Comparison WBC and Platelet Count from September, 2017 through December, 2017

DATE	WBC Count	Platelet Count	
September, 2017	6.04	206	Before ***ImunStem***
December, 2017	9.60	254	After ***ImunStem***

m) R.H. is a 54-year-old white male was diagnosed in December 26, 2016 with esophageal cancer in stage two (2) after the patient collapsed for no apparent reason and began spewing blood. The patient was rushed to the local emergency room where testing immediately began and the diagnosis was made. The patient refused standard medical cancer treatment (chemotherapies).

The patient began taking ***ImunStem*** in February 20, 2017, and shown improvements in both reports the blood reports and medical scans. The physician at the hospital after reviewing the blood report and medical scans his recommendation "resume regular diet" and to receive another checkup in four (4) weeks. Please see table below as following:

Comparison WBC, Mean Platelet Volume and Platelet from January, 2017 through March, 2017

DATE	WBC	Mean Platelet Volume	Platelet	
January, 2017	6.40	6.90	375	Before ***ImunStem***
March, 2017	9.40	8.40	332	After ***ImunStem***

16.0 HOW SUPPLIED/STORAGE AND HANDLING

16.1 Storage and Stability

STORAGE: Store material at controlled room temperature 20°C (68°F).

STABILITY: ***ImunStem*** is chemically stable for one (1) year at room temperature. Do not freeze.

16.2 Medicine Classification

Prescription Medicine.

16.3 Packaging

SERVING PER CONTAINER: Boston round one (1fl.oz.) fluid ounce amber glass bottle 20mm-40 Neck Finish. Cap with cap band.
DROPPER ASSEMBLY: 20/400 black FRST PP closure; SR20 (1cc) black flouroglazed monprene buld; 7x76mm straight tip TYPE III (soda lime) glass pipette.

17.0 PATIENT COUSELLING INFROMATION

17.1 Administration

- Inform patients to shake bottle well before using and take ½ to ¾ quarter of a dropper of ***ImunStem*** under tongue. Leave under tongue for approx forty (40) seconds and then drink water.
- Advise patients that ***ImunStem*** is present in liquid form consistency, and is administered orally. At present it is recommended in this form only.
- Instruct patients if an oral administration of ***ImunStem*** is necessary yet the patient has a sensitivity of the mouth and/or throat then an administration orally mixed between one (1) teaspoonful of yogurt can be administered.

ImunStem is an herbal (botanical) drug substance that is derived from Olive leaf, Yarrow flowers, Rosemary leaf, Yucca plant and Cassia oil.

Manufacturing by: Golden Sunrise Pharmaceutical Incorporation
P.O. Box 510
Porterville, CA 93258
Part No.: GS-00001 / Revised: 01/2018

DOCUMENT INFORMATION PAGE

DARRTS COMMUNICATION

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	PIND 117507
Communication Type:	Correspondence
Communication Group:	IND Information Request or Advice
Communication Name:	Advice/Information Request [Pre-IND]
Communication ID:	COR-INDAD-02
Drafted by:	kdwinestock
Clearance History:	
Finalized:	
Filename:	
Use Statement:	Use to send the sponsor either advice or a request for additional information
Notes:	This version is for INDs in PRE-SUBMISSION status (i.e., PIND).

Version: DARRTS 09/28/2010

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

MEMORANDUM OF TELECON

Application Number	PreIND 117507
Product	ImunStem
Sponsor	Golden Sunrise Pharmaceuticals, Inc.
Indication	Serious and Life Threatening Conditions

Purpose	To discuss the type of application submitted and the indication sort	**Telecon Date**	January 15, 2013
Details of Telecon Agreement	During this teleconference Mr. Huu S. Tieu, the authorized representative for Golden Sunrise Pharmaceuticals, was informed that the agency could not determine which type of application had been submitted. The cover letter identified the submission as a NDA, but a 356H form and user fee cover sheet had not been submitted. Mr. Tieu stated he was unaware of the fee requirement for NDA applications and he inquired about the amount that was due. I noted that an IND form 1571 was included along with a request for emergency use. Based upon the information on the 1571, the sponsor was seeking an indication to treat serious and life-threatening conditions. I informed him that the sponsor could not seek an indication for serious and life threatening conditions for an IND nor an NDA. If the submission is an IND, he would need to submit a separate IND based upon the indication sort. The IND would be reviewed by the appropriate division in CDER. After further discussions, I determined that the sponsor had not conducted any controlled clinical trials. The clinical data submitted with this application was from at least 18 patients with various life threatening conditions (seizure disorders, chronic hepatitis C, Parkinson's Disease, hypertension, various forms of cancer, etc) who had received ImunStem over the past several years. Mr. Tieu was informed that the data submitted, could not support an IND application nor an NDA I stated the sponsor needed data from clinical trials to support these types of applications. Since clinical trials had not been conducted, a request for a preIND meeting would be needed to discuss the sponsor's development plans. I noted that the sponsor appeared to have provided this drug to a number of patients with various types of cancers and asked whether the sponsor planned to pursue an oncology drug development program first. Mr. Tieu stated that the sponsor wanted to pursue chronic hepatitis C drug development. I stated that the Division of Antiviral Products would assign a preIND number to this submission, however, the sponsor needed to review the Guidance for Industry document regarding requesting meetings with the agency. The meeting request should include summary product quality, nonclinical, and clinical data if available. A list of questions as well as a protocol synopsis should be included with the request. I also stated he needed to review the Guidance regarding submission of IND applications. In addition, the sponsor should consider working with a consultant familiar with IND and NDA drug development to assist with assembling a comprehensive meeting request and future IND application.		

	Mr. Tieu agreed to discuss these issues with his colleagues and submit a PreIND meeting request along with the background documents.
Sponsor Representative(s)	Huu S. Tieu, Presiden/CEO
FDA Representative(s)	Karen Winestock, Chief, Project Management Staff, DAVP
RPM	

RPM Signature: *{See appended electronic signature page}*

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN D WINESTOCK
02/27/2013

DOCUMENT INFORMATION PAGE

DARRTS COMMUNICATION

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	PIND 117507
Communication Type:	Correspondence
Communication Group:	PIND Acknowledgement
Communication Name:	Acknowledge Pre IND
Communication ID:	COR-INDACK-07
Drafted by:	Kdwinestock, 2.14.13
Clearance History:	
Finalized:	Kdwinestock 2.14.13
Filename:	
Use Statement:	
Notes:	

Version: DARRTS 08/24/2010

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

PIND 117507

PRE-IND ACKNOWLEDGEMENT

Golden Sunrise Pharmaceutical, Inc.
Attention: Huu S. Tieu
CEO and President
560 W. Putnam Avenue, Suite 2
Porterville, CA 93257

Dear Mr. Tieu:

We acknowledge receipt of your January 7, 2013, submission concerning ImunStem. This submission contains product quality, genotoxicity data and individual subject summaries for subjects with various life threatening conditions who have received ImunStem.

Please refer to the January 15, 2013 telephone conference between you and Ms. Karen Winestock, Chief, Project Management Staff, Division of Antiviral Products, during which you were informed that your submission did not meet the standards for a New Drug Application (NDA) because essential data (e.g., 356H form, User Fee Cover Sheet, user fee payment, data from controlled clinical trials, etc) was not included with your submission.

In addition, you included a 1571 form with your submission, but a 1571 form must be submitted with an Investigational New Drug Application (IND). You were also informed during the call that the submission did not meet the standards for an IND application because 18 volumes of your 22 volume submission contained individual subject history information for 18 subjects suffering from various serious and life threatening conditions, a protocol for a clinical trial in a specific patient population (chronic hepatitis C, colon carcinoma, Parkinson's disease, etc.) was not submitted nor did you identify the indication you planned to pursue. You were informed that you need to specify the serious and life-threatening condition (hepatitis C, Parkinson's disease, colon cancer, etc) you plan to treat so your submission can be reviewed by the appropriate review division in the Center for Drug Evaluation and Research.

We have opened a Pre-Investigational New Drug Application (PIND) file for this drug product. Please note the following identifying data:

PIND Number Assigned: 117507

Sponsor: Golden Sunrise Pharmaceutical, Inc.

Name of Drug: ImunStem

Please submit a request for PreIND consultation. Your request should include a list of questions, nonclinical summary data, summary chemistry manufacturing and control data, a summary of previous human experience, and a protocol or protocol synopsis. For information regarding the content and format of meeting requests, please see "Guidance for Industry, Formal Meetings Between the FDA and Sponsors or Applicants
http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf.

In addition, please consult the Guidance for Industry, Botanical Drug Products for information http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070491.pdf.

This PreIND is for your chronic hepatitis C drug development program. No additional indications can be discussed under this PreIND.

Forward all future communications concerning this PIND in triplicate, identified by the above PIND number, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Studies in humans may not be conducted under this PIND. Before you may conduct studies in humans, you must submit a full Investigational New Drug Application (IND, see 21 CFR Part 312, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm) by amending this PIND with the required information. Include the above PIND number in Box 6 of the form FDA 1571 submitted with your IND. Send your IND submission in triplicate to the above address.

If you have any questions, call me, at (301) 796-0834 or 301-796-1500.

Sincerely,

{See appended electronic signature page}

Karen Winestock
Chief, Project Management Staff
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN D WINESTOCK
02/27/2013

DOCUMENT INFORMATION PAGE

DARRTS COMMUNICATION

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	PIND 117507
Communication Type:	Correspondence
Communication Group:	Meeting
Communication Name:	Meeting Request Granted [WRITTEN RESPONSES ONLY]
Communication ID:	(COR-MEET-01) (COR-BLAMEET-01)
Drafted by:	Kdwinestock, 2.28.13
Clearance History:	
Finalized:	Kdwinestock, 2.28.13
Filename:	
PDUFA Goal Impact:	Closes meeting response goal
Use Statement:	This letter is to be used for granting written responses in lieu of a sponsor meeting **ONLY** for Type C and PIND meeting requests.
Notes:	Do not use for a biosimilar biological product meeting request. Use the Biosimilar Meeting Request Granted Letter (COR-MEET-01)

Version: DARRTS 10/01/2012

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

PIND 117507

MEETING REQUEST GRANTED
WRITTEN RESPONSES ONLY

Golden Sunrise Pharmacueticals
Attention: Mr. Huu Tieu
President
P.O. Box 510
Porterville, CA 93528

Dear Mr. Tieu

Please refer to your Pre-Investigational New Drug Application (PIND) file for ImunStem.

We also refer to your February 6, 2013, February 15, 2013 and February 20, 2013, correspondence requesting a meeting to discuss the data needed to support an IND application. Based on the statement of purpose, objectives, and proposed agenda, we consider the meeting a Pre-IND meeting.

We have determined that written responses to your questions would be the most appropriate means for responding to the meeting request. Therefore, a meeting will not be scheduled. Our goal date for providing our written responses is April 22, 2013.

We acknowledge receipt of your briefing document. However, eight desk copies or one electronic copy of your January 7, 2013 submission is needed.

Submit eight desk copies or one electronic copy to the following address:

Karen Winestock
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6322
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

If you have any questions, call me at (301) 796-0834 or 301-796-1500.

Sincerely,

{See appended electronic signature page}

Karen Winestock
Chief, Project Management Staff
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN D WINESTOCK
02/28/2013

DOCUMENT INFORMATION PAGE

DARRTS COMMUNICATION

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	PIND/117507
Communication Type:	Correspondence
Communication Group:	Meeting
Communication Name:	Meeting Minutes
Communication ID:	(COR-MEET-09) (COR-BLAMEET-08)
Drafted by:	Kdwinestock, 3.29.13
Clearance History:	R. Fleischer, 4.4.13, 4.15.13 K.M. Wu, 4.5.13, 4.15.13 H. Ghantous, 4.15.13, 4.16.13 S. Miller, 4.5.13,4.15.13 J. O'Rear, 4.17.13 N. Battula, 4.11.13, 4.15.13, 4.17.13 V. Arya, 4.16.13 I. Younis, 4.16.13 J. Dou, 4.5.13, 4.15.13 J. Murray, 4.18.13 S. Chen, 4.15.13 C. Wu R. Madurawe, 4.18.13
Finalized:	Kdwinestock 4.18.13
Filename:	
PDUFA Goal Impact:	Closes the meeting minutes goal
Use Statement:	Use to send the official written responses to sponsor when a written response only is granted for PIND or Type C meetings. For meetings where a discussion is held with the sponsor, use (COR-MEET-03) (COR-BLAMEET-03).
Notes:	

Version: DARRTS 02/04/2013

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

PIND 117507

MEETING REQUEST - WRITTEN RESPONSES

Golden Sunrise Pharmaceuticals
Attention: Mr. Huu S. Tieu
President
P.O. Box 510
Porterville, CA 93528

Dear Mr. Tieu:

Please refer to your Pre-Investigational New Drug Application (PIND) file for ImunStem.

We also refer to your submission dated February 20, 2013, containing a pre-IND meeting request. The purpose of the requested meeting was to discuss the information needed to support an IND application.

Further reference is made to our Meeting Granted letter dated February 28, 2013, wherein we stated that written responses to your questions would be provided in lieu of a meeting.

The enclosed document constitutes our written responses to the questions contained in your background package.

If you have any questions, call Karen Winestock, Chief, Project Management Staff, at (301) 796-0834 or 301-796-1500.

Sincerely,

{See appended electronic signature page}

Russell Fleischer, PA-C, MPH
Senior Clinical Analyst
PreIND Team Leader
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:
Written Responses

WRITTEN RESPONSES

Meeting Type: B
Meeting Category: Pre-IND

Application Number: PIND 117507
Product Name: ImunStem
Indication: Treatment of chronic hepatitis C (CHC)
Sponsor/Applicant Name: Golden Sunrise Pharmaceuticals
Regulatory Pathway: 505(b)(1)

1.0 BACKGROUND

Golden Sunrise Pharmaceuticals is currently marketing ImunStem, a botanical product that is comprised of olive leaf extract, yarrow extract, and rosemary extract, under the dietary supplement guidelines. Golden Sunrise is now interested in developing ImunStem as a drug product for treatment of serious and life-threatening illnesses. Based upon the information provided in the background package, at least 18 patients with a serious and life-threatening condition (hepatitis C, esophageal cancer, glioblastoma, Parkinson's disease, epilepsy, rectal adenocarcinoma, etc.) have received treatment with ImunStem. Golden Sunrise Pharmaceuticals requested a PreIND (PIND) meeting to reach agreement on the acceptability of their plan to conduct a phase 2b clinical trial based upon the previous human experience data obtained to date as a treatment for patients with chronic hepatitis C (CHC).

2. QUESTIONS AND RESPONSES

General

Based on our review of your PIND backgrounder, we find no evidence that ImunStem had any effect on the immune system of treated patients or that it can engulf bacteria, kill parasites, identify and eliminate tumor cells, or kill viral-infected cells.

Further, the proposed endpoints of increase in balance, and alertness are not scientifically rigorous to support any indication for ImunStem for the treatment of patients with chronic hepatitis C.,

Clinical

Question 1: **Can Golden Sunrise waive the phase 1 clinical study for ImunStem submission based on the evidence of positive medical results for safety? Please refer to submission package dated January 7, 2013 Volume V thru XXII of XXII. NOTICE: These volumes contain patients treated with ImunStem in Serious or Life-threatening conditions in which no adverse side effects were observed by their physicians".**

FDA Response: No, the phase 1 clinical study requirement cannot be waived. As discussed above there is no evidence that ImunStem has any antiviral or immunologic activity in patients with CHC, or that the dose and dosing regimen are appropriate.

The extensive human use of olive leaf, yarrow and rosemary may support that ImunStem can be well tolerated by the general population at 0.5 ml or up to a few milliliters without serious adverse effects. However, allergic reactions (due to yarrow) for yarrow have been reported. For treatment of patients with serious or life-threatening diseases, you should provide additional scientific justifications in terms of safety and potential usefulness. Please see the Pharmacology/Toxicology section below for more specific guidance.

Question 2. Can Golden Sunrise waive the phase 2 clinical study for ImunStem submission based on the evidence of oral liquid dosage? Please refer to submission package date January 7, 2013 Volumes V thru XXII of XXII. NOTICE: These volumes contain patients treated with ImunStem in Serious or Life-threatening conditions using a optimal dosage measurement of (0.50 ml) up to four (4) doses daily in which no adverse side effects were observed by their physicians". The prescribed standard dosage for ImunStem; 0.50 ml sublingual, hold for 30 to 40 seconds then swallow. Taken up to four (4) times per day, has yielded favorable clinic results across study subjects. In reference to the submission dated January 07, 2013, Volumes X, XII and XIV of XXII the results reflected on mitigating patient symptom report and declining viral loads infers evidence that ImunStem has potential clinical benefit.

FDA Response: No. Overall, we find that you have not provided adequate safety information to support the proposed dose of 25 ml ImunStem for patients with CHC. For a sublingual "supplement" dose of 0.5 ml ImunStem, the previous human use may be adequate to support its safety. We note that different doses for different durations were used in different populations of patients treated with ImunStem. For example, the "Description Section of ImunStem Liquid for Oral Solution" recommends 25 ml as described above; however, one patient applied a much higher dose (50 ml of ImunStem 4 times daily, Volume 13, page 6). The "ImunStem Supplement Label" (Attachment 4.6, Vol. 1), provides recommended use of "0.5 ml of ImunStem under tongue." Therefore, you must conduct adequate and well-controlled studies to determine the appropriate dose and duration of ImunStem, as well as an evaluation of the safety of the product.

Question 3. Based on the above evidence can Golden Sunrise be granted approval to proceed with phase IIb clinical study Hepatitis "C" Chronic?

FDA Response: No. DAVP reviewed the case reports of the three patients with CHC, and in none was there evidence of activity (e.g., sustained reduction in HCV RNA and/or normalization of transaminase levels). The claim that patients felt better and had increased energy and mental clarity are not acceptable when there is no evidence of clinically relevant antiviral activity.

The case reports are inadequate and fail to provide important information about safety and efficacy. It is not acceptable to submit only laboratory reports to support a claim of efficacy.

It appears each of these patients was inappropriately treated under the protocol. None of the patients' cases reviewed suggested they were in need of the "emergency" use of ImunStem. Under section 2.1 of the protocol, patients must have a serious and life-threatening disease or condition with no approved alternative therapy and no time to obtain FDA approval. DAVP acknowledges that CHC is a serious and life-threatening illness. However, it may take greater than 20 years for an infected patient to manifest signs and symptoms of end-stage liver disease, and in each case the patients you treated had alternative therapies available and none were in imminent risk of death.

Should ImunStem progress into clinical trials, you will need to redesign the protocol to contain at a minimum:

- Explicit inclusion and exclusion criteria for treatment of chronic CHC. Such disease-specific inclusion criteria should include a specific definition of CHC, genotype and viral load requirements, treatment history, and histology.
- A specified dose and dosing regimen.
- Objective and measurable endpoints consistent with response to treatment, such as undetectable HCV RNA at 12 and 24 weeks following a defined course of therapy.
- An objective and systematic method for assessing adverse events.

If you wish to pursue use of ImunStem as a potential therapy for treatment of chronic CHC, you must submit more data on the product's proposed mechanism of action, support for the proposed doses, and objective safety and efficacy endpoints to be evaluated.

Once you have successfully addressed all the items listed above and below, you may be able to conduct a small well-designed study in a few patients.

2.1. Additional FDA Comments

Insufficient information regarding the pharmacology/toxicology, chemistry, manufacturing, and controls (CMC) was available in your submission for the safety and quality assessment of your product. To support submission of an IND, you need to provide the following information:

Chemistry, Manufacturing, and Controls

Botanical

1. Provide the scientific names and medicinal parts used for olive leaf, yarrow, and rosemary, respectively. For each botanical raw material, more detailed morphological description should be provided. The FT-IR spectra provided alone as identity tests for the botanical raw materials are not adequate. Other more specific methods (such as HPLC with reference standards of the three known chemical markers and/or fingerprints of authenticated botanical raw materials) are recommended.

2. Provide the extraction methods for the manufacturing of olive leaf extract, yarrow extract, and rosemary extract. At the minimum, you should provide the solvent used,

herb and solvent ratios, the yields of the extractions, and equivalent raw herb weight in each ml/dose of ImunStem.

3 Provide data to support the classification of the three compounds as the active molecules of ImunStem, while other components (such as [redacted]TS) are considered as "inactive ingredients".

Product Quality

4. The composition of the finished product should be fully described, with quantitative amounts or suitable ranges for each component that remains in the finished product. Refer to the document "Guidance for Industry - Botanical Drug Products" for details. It is not clear from the information in Attachements 4.1 and 4.2 whether significant amounts of the [redacted]TS remain in the finished product. Additionally, the Ingredient Lists for ImunStem and OVE-60 in Attachment 4.2 cannot be reconciled with the ImunStem components in Attachment 4.1.

5. See the guidance entitled "Guidance for Industry – Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products" for other CMC recommendations such as stability information which are not included in this submission.

Pharmacology/Toxicology

6. Conduct extensive toxicology literature search on the toxicity profiles of olive leaf, rosemary, and yarrow extracts, which are used for ImunStem, in animals and present them in full details in your initial IND submission. Statements such as "non-toxic" and "Gras" are not informative and not acceptable (any chemical at sufficiently high doses could elicit organ/system toxicity, which is what is needed in the IND submission). List all known phytochemical molecules and the percentage contained in the olive leaf, rosemary, and yarrow extracts that you have used for your product, as some of them may be the causative agents for potential adverse effects of ImunStem in humans.

Virology

7. Please initiate studies to evaluate the anti-HCV activity and the mechanism of ImunStem anti-HCV activity and include complete study reports in the IND submission. The EC_{50} value of ImunStem should be determined for those HCV genotypes/subtypes you propose to study in your clinical trials and the lot-to-lot variability in antiviral activity assessed. To facilitate in the conduct of your non-clinical studies, please refer to the virology guidance sent to you in the letter dated February 22, 2010.

8. If ImunStem displays anti-HCV activity, then select for resistant HCV replicons or virus, as appropriate, and characterize the isolates genotypically and phenotypically with respect to resistance. These studies should be conducted prior to dosing infected individuals.

9. Compare the ImunStem resistant replicons/virus to those of the direct-acting anti-HCV agents to determine the cross-resistant potential of ImunStem. These studies should be conducted prior to dosing infected individuals.

10. In cell culture studies, determine the combination antiviral relationships of ImunStem with approved drugs for the treatment of chronic HCV infection. These studies should be conducted prior to combination therapy with approved drugs for HCV.

For development beyond initial Phase 1 studies, the following information should be provided:

11. Establish a chemical assay method for active constituents or characteristic markers for each botanical component, including [redacted TS] extract in addition to the three botanical materials that you have classified as active ingredients.

12. The manufacturing process for the five botanical extracts should be described in sufficient detail. This should include:
    a. The solvents or other materials used, including those that are removed subsequently (for example, by distillation) so that appropriate controls on strength, composition and impurities (such as heavy metals, pesticides and other contaminants) can be established
    b. The composition of complex non-botanical components such as [redacted TS]

13. Establish a specification for the finished product which should include appropriate tests, acceptance criteria and references to the analytical procedures. The table of In-Process Controls on Page 11 of the briefing package is not appropriate since it does not have suitable tests to verify identity, potency of the main ingredients that are believed to be active, etc.

14. Each component used to manufacture the drug product should have appropriate controls to verify its identity and suitability. This is especially important for components that are not typically used for pharmaceuticals, and therefore have no compendial monographs

Pharmacology/Toxicology

15. Please follow ICH and FDA guidance when planning the necessary nonclinical toxicity studies in support of the next advanced phase development of ImunStem (ref. ICH-M3: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073246.pdf)

16. With regard to your genotoxicity (AMES) test, please request your contract laboratory to certify that it was conducted according to ICH-S2 guidance. The dose selection in your AMES test was inadequate and the concentrations of three botanical extracts should be proportionally (e.g., 70:16:14 as reflected in you final product) escalated to cytotoxic or

maximally soluble levels (up to 5mg total extracts in combination/plate), instead of serial dilutions of the product.

PREA REQUIREMENTS

Please be advised that under the Food and Drug Administration Safety and Innovation Act (FDASIA), you must submit a Pediatric Study Plan (PSP) within 60 days of an End-of-Phase 2 (EOP2) meeting held on or after November 6, 2012. If an EOP2 meeting occurred prior to November 6, 2012 or an EOP2 meeting will not occur, then:

- if your marketing application is expected to be submitted prior to January 5, 2014, you may either submit a PSP 210 days prior to submitting your application or you may submit a pediatric plan with your application as was required under the Food and Drug Administration Amendments Act (FDAAA).
- if your marketing application is expected to be submitted on or after January 5, 2014, the PSP should be submitted as early as possible and at a time agreed upon by you and FDA. We strongly encourage you to submit a PSP prior to the initiation of Phase 3 studies. In any case, the PSP must be submitted no later than 210 days prior to the submission of your application.

The PSP must contain an outline of the pediatric study or studies that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation, and any previously negotiated pediatric plans with other regulatory authorities. For additional guidance on submission of the PSP, including a PSP Template, please refer to: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm . In addition, you may contact the Pediatric and Maternal Health Staff at 301-796-2200 or email pdit@fda.hhs.gov.

DATA STANDARDS FOR STUDIES

CDER strongly encourages IND sponsors to consider the implementation and use of data standards for the submission of applications for investigational new drugs and product registration. Such implementation should occur as early as possible in the product development lifecycle, so that data standards are accounted for in the design, conduct, and analysis of clinical and nonclinical studies. CDER has produced a web page that provides specifications for sponsors regarding implementation and submission of clinical and nonclinical study data in a standardized format. This web page will be updated regularly to reflect CDER's growing experience in order to meet the needs of its reviewers. The web page may be found at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm

This PreIND is for your chronic hepatitis C drug development program. No additional indications can be discussed under this PreIND.

Forward all future communications concerning this PIND in triplicate, identified by the above PIND number, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Studies in humans may not be conducted under this PIND. Before you may conduct studies in humans, you must submit a full Investigational New Drug Application (IND, see 21 CFR Part 312, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm) by amending this PIND with the required information. Include the above PIND number in Box 6 of the form FDA 1571 submitted with your IND. Send your IND submission in triplicate to the above address.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL D FLEISCHER
04/19/2013

DOCUMENT INFORMATION PAGE

DARRTS COMMUNICATION

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	IND 117507
Communication Type:	Correspondence
Communication Group:	
Communication Name:	
Communication ID:	
Drafted by:	Kdwinestock, 12.13.13
Clearance History:	R. Fleischer, 12.13.13
Finalized:	Kdwinestock, 12.13.13
Filename:	
Use Statement:	Use to document a non-PDUFA teleconference with a sponsor/applicant and meeting minutes will NOT be sent.
Notes:	Check into DARRTS as a Correspondence and use the appropriate Correspondence function code (e.g., Information Request/Advice) and sent via VERBAL. For additional instructions, please see: http://inside.fda.gov:9003/downloads/CDER/OfficeofBusinessProcessSupport/UCM210177.pdf

Version: DARRTS 7/11/2013

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

MEMORANDUM OF TELECONFERENCE

Teleconference Date: December 12, 2013

Application Number: IND 117507
Product Name: ImmunStem
Sponsor/Applicant Name: Golden Sunrise Pharmaceuticals

Subject: IND 117507, supporting document 7, dated November 15, 2013

FDA Participants :
1. Russell Fleischer, PA-C, MPH, PreIND Team Leader
2. Karen Winestock, Chief, Project Management Staff, DAVP

Sponsor/Applicant Participants
1. Huu S. Tieu

BACKGROUND: Golden Sunrise Pharmaceuticals is currently marketing ImmunStem as a botanical dietary supplement. The applicant would like to market this product as a prescription drug. On February 20, 2013, the sponsor submitted a request for PreIND consultation and in response to the request the Agency agreed to provide written responses to the sponsor. The responses were provided to the sponsor on April 9, 2013. On November 22, 2013, the Agency received the November 15, 2013 submission from Golden Sunrise Pharmaceutical, which according to the sponsor, addressed all of the issues listed in the FDA's April 9, 2013 communication.

This telecon was requested by the Agency to discuss clinical information that was included in the submission.

Note: The telephone conference began with FDA introductions, followed by introductions by representatives from Golden Sunrise Pharmaceuticals. At the beginning of the call, Mr. Huu S. Tieu was the only company participant, but approximately 15 minutes into the call, the FDA participants could hear Mr. Tieu whispering to someone else at his location. We asked him to identify the other participant and at that time we were informed that Mr. Edgar Ayala had joined the discussion.

2.0 DISCUSSION:

The FDA stated they had serious concerns related to the product. During the review of the submission, the clinical reviewer identified a number of claims that appeared in the Investigator's Brochure that were in the realm of prescription drug claims, despite this product being marketed as a dietary supplement. The Agency stated that it is illegal to make drug claims when a sponsor is marketing a dietary supplement. The FDA highlighted the following claims that were included in the Investigator's Brochure:

- ImmunStem crosses the blood brain barrier.
- ImmunStem improves the immune system.
- ImmunStem is quite effective in reducing the Hepatitis C and allowing the body's immune system to control the virus and repair damage done to the body

The FDA noted that the claims listed above are structure function claims and they cannot be used when a sponsor is marketing a product as a dietary supplement. In addition, to date, the sponsor has not provided any data that supports these claims.

Data from patients infected with the Hepatitis C virus has been reviewed; these data consisted mostly of subjective assessments and laboratory data. These data failed to demonstrate any effect on the virus. To date, the Agency has not received any preclinical or clinical antiviral activity data that supports the sponsor's contention that ImmunStem has an effect on the HCV virus. The Agency noted that data from a patient with the glioblastoma shows the patient died seven days after receiving ImmunStem and no effect on the patient's condition was identified.

The Agency cautioned the sponsor about making these types of claims in their documents. In addition, the sponsor had not addressed any of the issues provided in two PreIND Written Response Only communications.

Mr. Ayala asked whether the patient's biomarker and laboratory data had been reviewed because he has reviewed the serology data and has been assessing the patients. Mr. Ayala noted that data had been submitted that shows at least two patients with hepatitis C have experienced a decrease in their viral load counts. Mr. Ayala inquired about the data needed to support the sponsor's claim of safety and efficacy in treatment of patients with chronic hepatitis C.

The FDA recommended the sponsor review the labeling of drugs that have been approved for the treatment of hepatitis to understand the amount of data necessary to support approval for this indication. The sponsor was advised to consult FDA guidance on development of therapies for hepatitis C. The sponsor was advised that in vitro virologic data from replicon systems and potential resistance should be evaluated prior to conducting clinical trials. Should the sponsor demonstrate the antiviral activity of ImmunStem, then clinical data from adequate and well-controlled trials are needed demonstrating a sustained viral response, ALT decease or normalization, adverse event information from patients with adverse liver function, and resistance data. The sponsor asked how many patients would need to be treated and FDA stated a database of at least 1500 patients would likely be needed. Since the sponsor has failed to address recommendations by FDA, FDA recommended the sponsor work with a consultant who is familiar with drug development. Further, if the sponsor plans to use patient reported outcomes, then an instrument will need to be developed and validated.

Mr. Ayala stated that he has been attending to the patients receiving ImmunStem and documenting their comments. The sponsor referenced the Agency's communications and noted that the Agency had accepted their submissions. The Agency noted that the communication only acknowledged receipt of the sponsor data, not acceptance of it. A heated discuss ensued during which the FDA representatives were accused of being rude and condescending to the sponsor.

At this point, the Agency was informed that the call was being recorded. The Agency noted that recording a telephone conversation without notifying the participants is illegal. The call was ended.

3.0 ACTION ITEMS:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN D WINESTOCK
12/23/2013

October 20, 2015

The below COR-NDAFILE-01 (Refuse to File) for NDA 204701 was issued in error. The appropriate user fee has not been received for this application, and therefore it was unacceptable for filing. The communication function of this letter has been changed to Advice. The related COR-NDAACK-11 (No User Fee Received) letter was issued on 10/19/2015.

DOCUMENT INFORMATION PAGE

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	NDA 204701
Communication Type:	Correspondence
Communication Group:	Filing
Communication Name:	Refuse to File
Communication ID:	(COR-NDAFILE-01) (COR-sNDAFILE-01) (COR-BLAFILE-01) (COR-sBLAFILE-01)
Drafted by:	
Clearance History:	
Finalized:	
Filename:	
Signatory Authority:	Division Director or Deputy. Person who is covering for the signatory authority can sign on their behalf (i.e., the signature block on the letter will not change).
Use Statement:	Use to Refusal-to-File an application that is too deficient to merit a substantial review.
Notes:	

Version: 08/07/2015

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204701

REFUSAL TO FILE

Golden Sunrise Pharmaceutical, Inc.
Attention: Huu S. Tieu
President/CEO
P.O. Box 510
Porterville, CA 93258

Dear Mr. Tieu:

Please refer to your New Drug Application (NDA) dated July 20, 2015, received July 28, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Imunstem.

After a preliminary review, we find your application is not sufficiently complete to permit a substantive review. Therefore, we are refusing to file this application under 21 CFR 314.101(d) for the following reasons:

- The application did not contain a completed application form (356h)
- The application was not submitted in the proper format required under 21 CFR 314.50
- The application is incomplete because it does not contain information required under section 505(b) of the act and 21 CFR 314.50
- The appropriate user fee for this application was never received

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. Additional information is available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to

set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

If you wish to send payment by wire transfer, or if you have any other user fee questions, please call the Prescription Drug User Fee staff at 301-796-7900.

Please note that this filing review represents a preliminary review of the application and is not indicative of deficiencies that would be identified if we performed a complete review.

Within 30 days of the date of this letter, you may request in writing a Type A meeting about our refusal to file the application. A meeting package should be submitted with this Type A meeting request. To file this application over FDA's protest, you must avail yourself of this meeting.

If, after the meeting, you still do not agree with our conclusions, you may request that the application be filed over protest. In that case, the filing date will be 60 days after the date you requested the meeting. The application will be considered a new original application for user fee purposes, and you must remit the appropriate fee.

PROPOSED PROPRIETARY NAME

If you intend to have a proprietary name for the above-referenced product, submit a new request for review of a proposed proprietary name when you resubmit the application. For questions regarding proprietary name review requests, please contact the OSE Project Management Staff via telephone at 301-796-3414 or via email at OSECONSULTS@cder.fda.gov.'

If you have any questions, call Elizabeth Thompson, Chief, Project Management Staff, at (301) 796-1500.

Sincerely yours,

{See appended electronic signature page}

Jeffrey S. Murray, M.D., M.P.H.
Deputy Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFREY S MURRAY
09/28/2015

DOCUMENT INFORMATION PAGE

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	NDA 204701
Communication Type:	Correspondence
Communication Group:	Acknowledgment
Communication Name:	No User Fee Received
Communication ID:	(COR-NDAACK-11)(COR-SNDAACK-12)(COR-BLAACK-11)(COR-SBLAACK-12)
Drafted by:	EGT October 19, 2015
Clearance History:	J. Murray
Finalized:	
Filename:	
Signatory Authority:	CPMS or RPM
Use Statement:	Use to notify the applicant that the application is unacceptable for filing because NO USER FEE has been received within 5 days of the FDA receipt date. Application should be accepted for filing if a fee is submitted, even if the amount is incorrect.
Notes:	

Version: 07/15/2015

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204701

UNACCEPTABLE FOR FILING

Golden Sunrise Pharmaceutical, Inc.
Attention: Huu S. Tieu
President/CEO
P.O. Box 510
Porterville, CA 93258

Dear Mr. Tieu:

Please refer to your New Drug Application (NDA) dated July 20, 2015, received July 28, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imunstem.

We also refer to our letter dated September 28, 2015. Your application is not refused to file as indicated in our letter, but instead unacceptable for filing. We have not received the appropriate user fee for this application. An application is considered incomplete and cannot be accepted for filing until all fees owed have been paid. Therefore, this application is not accepted for filing. We will not begin a review of this application's adequacy for filing until FDA has been notified that the appropriate fee has been paid. Payment should be submitted to the following address:

Food and Drug Administration
P.O. Box 979107
St. Louis, MO 63197-9000

Checks sent by courier should be addressed to:

U.S. Bank
Attention: Government Lockbox 979107
1005 Convention Plaza
St. Louis, MO 63101

When submitting payment for an application fee, include the User Fee I.D. Number, the Application number, and a copy of the appropriate user fee coversheet (Form 3397 or 3792) with your application fee payment. When submitting payment for previously unpaid product and establishment fees, please include the Invoice Number(s) for the unpaid fees and the summary portion of the invoice(s) with your payment. The FDA P.O. Box number P.O. Box 979107 should be included on any check you submit.

The receipt date for this submission (which begins the filing review) will be the date the review division is notified that payment has been received by the bank. Please notify me when the appropriate user fees have been sent.

If you decide to pay the user fees for this application, please address all deficiencies/issues listed in our letter dated September 28, 2015. Please cite the NDA number listed above at the top of the first page of all submissions to this application. Unless you are using the FDA Electronic Submissions Gateway (ESG), send all submissions by overnight mail or courier to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. Additional information is available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

If you wish to send payment by wire transfer, or if you have any other user fee questions, please call the Prescription Drug User Fee staff at 301-796-7900.

If you have any questions regarding this application, contact me at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Elizabeth Thompson, M.S.
CDR, U.S. Public Health Service
Chief, Project Management Staff
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ELIZABETH G THOMPSON
10/19/2015

DOCUMENT INFORMATION PAGE

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	NDA 204701
Communication Type:	Correspondence
Communication Group:	Meeting
Communication Name:	Meeting Request Denied
Communication ID:	(COR-MEET-02) (COR-BLAMEET-02)
Drafted by:	
Clearance History:	
Finalized:	
Filename:	
Signatory Authority:	CPMS or RPM
Use Statement:	Use to notify the applicant that the requested meeting has NOT been granted because either meeting is not necessary or is premature. This letter includes an option to send the applicant comments and/or responses to submitted questions.
Notes:	Do not use for a biosimilar biological product meeting request. Use the Biosimilar Meeting Request Denied Letter (COR-MEET-02).

Version: 04/27/2015

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204701

MEETING DENIED

Golden Sunrise Pharmaceutical, Inc.
Attention: Huu S. Tieu
President/CEO
P.O. Box 510
Porterville, CA 93258

Dear Mr. Tieu:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imunstem.

We also refer to your October 30, 2015, correspondence requesting a type A meeting to discuss the confirmation of the regulatory mechanism for marketing approval of Imunstem. We are denying the meeting for the following reasons:

1. Lack of a complete NDA submission. We need a specific indication or indications proposed (serious and life-threatening diseases or conditions is not an indication because it is too broad). In addition, we need data/information to support an indication. In order to provide you with proper guidance, we need a specific disease identified. We do not agree to have a meeting under an NDA for which there is no single proposed indication, nor information to support a drug application for approval.

2. Please refer to your Pre-IND (PIND) 117507 and our written responses dated April 19, 2013. In addition, refer to the teleconference on December 2, 2013. A PIND mechanism is the best route for you to obtain feedback, before submission of an NDA. After you identify a specific disease/condition that your product may treat or prevent, a meeting request can be granted under a PIND with the appropriate review Division for discussion. If you plan to propose a meeting for an indication that is not reviewed under the Division of Antiviral Products, you will need to request a meeting from that specific review division.

If you have any questions, call me at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

CDR Elizabeth Thompson, MS
Chief, Project Management Staff
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ELIZABETH G THOMPSON
11/13/2015